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

Thursday, March 16, 2017

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

# **APPROVED MINUTES**

# I. Call to Order & Introductions

Chairperson Keshishian called the meeting to order at 9:34 a.m.

# A. Members Present:

Marc Keshishian, MD, Chairperson Suresh Mukherji, MD, Vice-Chairperson Denise Brooks-Williams Gail J. Clarkson, RN James B. Falahee, Jr., JD Debra Guido-Allen, RN Robert Hughes Jessica Kochin Thomas Mittelbrun Luis Tomatis, MD

# B. Members Absent:

Kathleen Cowling, DO

# C. Department of Attorney General Staff:

Joseph Potchen

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

Tulika Bhattacharya Matt Lori Amber Myers Beth Nagel Tania Rodriguez

# II. Review of Agenda

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

#### III. Declaration of Conflicts of Interests

None.

# IV. Review of Minutes of January 26, 2017

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

# V. Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services – Draft Language & Public Hearing Report

Ms. Nagel gave an overview of the public hearing (Attachment A), the draft language (Attachment B) and the Department's recommendations.

#### A. Public Comment

Robert Meeker – Greater Michigan Lithotripsy John Shaski – Sparrow Health System Doug Stairs – United Medical Systems

# B. Commission Discussion

Discussion followed.

#### C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Mukherji to take proposed action on the language presented today with proposed changes and move to Public Hearing and forward to the Joint Legislative Committee (JLC). The motion was amended to include a call to all parties to present information, data and testimony at the public hearing. Motion carried in a vote of 10- Yes, 0- No, and 0- Abstained.

# VI. Nursing Home and Hospital Long-Term-Care Unit (NH-HLTCU) Beds – Final Report & Draft Language

NH-HLTCU Workgroup Chair, Marianne Conner, gave an overview of the workgroup process, recommendations made according to the charge to the workgroup, and the draft language (see Attachments C and D).

# A. Public Comment

None.

#### B. Commission Discussion

Discussion followed.

# C. Commission Action

Motion by Commissioner Clarkson, seconded by Commissioner Brooks-Williams to accept the workgroup's recommended draft language as presented and send to a Public Hearing and JLC. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

# VII. Bone Marrow Transplantation (BMT) Services Draft Language

Ms. Nagel gave an overview of history of BMT standards and the draft language (see Attachment E).

# A. Public Comment

- 1. Muneer Abidi, M.D. Spectrum Health
- 2. Dennis McCafferty Economic Alliance for Michigan
- 3. Edward Peres, M.D. Henry Ford Health System
- 4. Justin Klamerus, M.D. Karmanos Cancer Center
- 5. Joseph Uberti, M.D. Karmanos Cancer Center
- 6. Greg Yanik University of Michigan Health System
- 7. Patrick O'Donovan Beaumont Health

# B. Commission Discussion

Discussion followed.

#### C. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner Falahee to not adopt the language as presented and leave the standard as is and revisit it in 2018 when it comes back up and take the time in between to come with something better perhaps than what we have today. Motion carried in a vote of 7 - Yes, 3 - No, and 0 - Abstained.

# VIII. Hospital Beds Standard Advisory Committee

Ms. Nagel gave an overview of the history of the agenda item. Mr. Potchen gave an update.

## A. Public Comment

- 1. Dennis McCafferty Economic Alliance of Michigan
- 2. Tony Denton University of Michigan Health System

### B. Commission Discussion

Discussion followed.

# C. Commission Action

Motion by Commissioner Mukherji seconded by Commissioner Brooks-Williams to create a Standard Advisory Committee and to charge the SAC to review all of the issues identified by the Department in the summary report presented at the January meeting with the exception of observation beds. Motion carried in a vote of 8 - Yes, 1 - No, and 0 - Abstained.

# IX. Legislative Report

Mr. Lori provided an overview of Legislative activity as it relates to Certificate of Need.

# X. Administrative Update

A. Planning & Access to Care Section Update

Ms. Nagel provided an update.

B. CON Evaluation Section Update

Ms. Bhattacharya provided an update on the following items:

- 1. Compliance Report (see Attachment F)
- 2. Quarterly Performance Measures (see Attachment G)
- 3. MRT Statewide Compliance Update (see Attachment H)
- 4. Update on Psychiatric Bed Special Pool (see Attachment I)

# XI. Legal Activity Report

Mr. Potchen provided an update on the CON legal activity.

XII. Future Meeting Dates: June 15, 2017, September 21, 2017, & December 7, 2017

Discussion followed.

# XIII. Public Comment

None.

# XIV. Review of Commission Workplan

Ms. Nagel provided an overview of the changes to the workplan (see Attachment J).

# A. Commission Discussion

Discussion followed.

# B. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner Hughes to accept the workplan as discussed. Motion carried in a vote of 9 - Yes, 0- No, and 0- Abstained

# XV. Election of Officers

Motion by Commissioner Falahee, seconded by Commission Clarkson, to nominate Commissioner Mukherji as the Chair of the Commission. Motion Carried in a vote of 9 – Yes, 0 – No and 0 – Abstained.

Motion by Commissioner Falahee, seconded by Commissioner Clarkson, to nominate Commissioner Mittelbrun as the Vice-chair of the Commission. Motion Carried in a vote of 9 – Yes, 0 – No and 0 – Abstained.

# XIV. Adjournment

Motion by Commissioner Mittlebrun, seconded by Commissioner Falahee, to adjourn the meeting at 12:32 p.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: February 13, 2017

TO: The Certificate of Need (CON) Commission

FROM: Beth Nagel, Division Director, Office of Planning, MDHHS

RE: Summary of Public Hearing Comments on Urinary Extracorporeal Shock

Wave Lithotripsy (UESWL) Services 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 UESWL Services Standards at its December 7, 2016 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed UESWL Services Standards on February 2, 2017. Written testimony was accepted for an additional seven days after the hearing. Testimony was received from two organizations.

# **Written Testimony:**

- 1.) John Shaski, Sparrow Hospital
  - Urges the adoption of a provision in the standard that would allow conversion from a mobile to a fixed UESWL unit.
- 2.) Alan Buergenthal, Greater Michigan Lithotripsy
  - Supports proposed changes to the standards that were presented at the December 2016 meeting.

# **Department Recommendation:**

The Department supports the language as presented at the December 7, 2016 CON Commission meeting. The Department also supports the testimony urging a conversion from a mobile to a fixed unit either for this update of the standard or in a later review.

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# MICHIGAN DEPARTMENT OF COMMUNITY HEALTH AND HUMAN SERVICES

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

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

#### Section 1. Applicability

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

#### Section 2. Definitions

- Sec. 2. (1) For purposes of these standards:
- (a) "Central service coordinator" OR "CSC" means the organizational unit that has operational responsibility for a mobile UESWL service and its unit(s) and that is a legal entity authorized to do business in the state of Michigan.
- (b) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.
- (c) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.
- (d) "Complicated stone disease treatment capability" means the expertise necessary to manage all patients during the treatment of kidney stone disease. This includes, but is not limited to:
- (i) A urology service that provides skilled and experienced ureteroscopic stone removal procedures and
  - (ii) Experienced interventional radiologic support.
- (e) "Department" means the Michigan Department of Community Health AND HUMAN SERVICES (MDCHMDHHS).
- (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.
- (I) "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) <u>EITHER Onon-site OR THROUGH A CONTRACTUAL AGREEMENT WITH ANOTHER HEALTH FACILITY</u>, 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) <u>EITHER Oon-site OR THROUGH A CONTRACTUAL AGREEMENT WITH ANOTHER HEALTH FACILITY, A</u> 23-hour holding unit.

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

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

UESWL service and its unit(s) from an existing site to a different site.

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- (1) "Upgrade an existing UESWL unit" means any equipment change, other than a replacement, that involves a capital expenditure of \$125,000 or less in any consecutive 24-month period.
  - (2) An applicant proposing to replace an existing UESWL unit(s) shall demonstrate the following:
- (a) Each existing UESWL unit of the service proposing to replace a UESWL unit has averaged at least 1,000 UESWL procedures per unit during the most recent continuous 12-month period for which the Department has verifiable data.
- (b) Each UESWL unit of the service proposing to replace a UESWL unit is projected to perform at least 1,000 UESWL procedures per unit per year pursuant to the methodology set forth in Section 10.
  - (3) An applicant proposing to replace a UESWL unit shall demonstrate one or more of the following:
  - (a) The existing equipment clearly poses a threat to the safety of the public.
- (b) The proposed replacement UESWL unit offers technological improvements that enhance quality of care, increase efficiency, or reduce operating costs and patient charges.
  - (c) The existing equipment is fully depreciated according to generally accepted accounting principles.
- (4) An applicant that demonstrates that it meets the requirements in this subsection shall not be required to demonstrate compliance with Section 4(2):
  - (a) The proposed project involves replacing 1 existing fixed UESWL unit with 1 mobile UESWL unit.
- (b) The proposed mobile unit will serve at least 1 host site that is located in a region other than the region in which the fixed UESWL unit proposed to be replaced is located currently.
- (c) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposed to operate when the results of the methodology in Section 10 are combined for the following, as applicable:
- (i) All licensed hospital sites committing MIDB data pursuant to Section 11, as applicable, that are located in the region identified in subsection (c).
- (ii) All sites that receive UESWL services from an existing UESWL service and propose to receive UESWL services from the proposed mobile unit and that are located in the region identified in subsection
- (d) A separate application from each host site is filed at the same time the application to replace a fixed unit is submitted to the Department.
- (e) The proposed mobile UESWL unit is projected to perform at least 1,000 procedures annually pursuant to the methodology set forth in Section 10.
- (5) An applicant proposing to relocate REPLACE its AN existing FIXED UESWL service and its unit(s) TO A NEW SITE shall demonstrate that the proposed project meets all of the following:
  - (a) The UESWL service and its unit(s) to be relocated is a fixed UESWL unit(s).
- (b)—The UESWL service to be relocated REPLACED has been in operation for at least 36 months as of the date an application is submitted to the Department\_UNLESS THE APPLICANT MEETS THE REQUIREMENT IN SUBSECTION (d)(i) OR (ii).
- (eb) The site to which the UESWL service will be relocated REPLACED meets the requirements of Section 3(1)(c).
- (dc) The proposed new site is in the state of Michigan and within a 25-mile radius of the existing site of the UESWL service to be relocated REPLACED.
- (ed) The UESWL service and its unit(s) to be relocated REPLACED performed an average of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data UNLESS ONE OF THE FOLLOWING REQUIRMENTS ARE MET:-
- (i) THE OWNER OF THE BUILDING WHERE THE SITE IS LOCATED HAS INCURRED A FILING FOR BANKRUPTCY UNDER CHAPTER SEVEN (7) WITHIN THE LAST THREE YEARS;
  - (ii) THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED
- WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL; OR
  - (iii) THE UESWL SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF AN ENTIRE HOSPITAL TO A NEW GEOGRAPHIC SITE AND HAS ONLY ONE (1) UESWL UNIT.

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

- (6) An applicant proposing to relocate REPLACE a fixed UESWL unit(s) of an existing UESWL service shall demonstrate that the proposed project meets all of the following:
- (a) The existing UESWL service from which the UESWL unit(s) is to be relocated REPLACED has been in operation for at least 36 months as of the date an application is submitted to the Department.
- (b) The site to which the UESWL unit(s) will be relocated REPLACED meets the requirements of Section 3(1)(c).
- (c) The proposed new site is in the state of Michigan and within a 25-mile radius of the existing site of the fixed UESWL unit to be relocated REPLACED.
- (d) Each existing UESWL unit(s) at the service from which a unit is to be relocated-REPLACED performed at least an average of 1,000 procedures per fixed unit in the most recent 12-month period for which the Department has verifiable data.
- (e) The applicant agrees to operate the UESWL unit(s) in accordance with all applicable project delivery requirements set forth in Section 9 of these Standards.
- (f) For volume purposes, the new site shall remain associated with the existing UESWL service for a minimum of three years.
- (7) Equipment that is replaced shall be removed from service and disposed of or rendered considerably inoperable on or before the date that the replacement equipment becomes operational.

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

- Sec. 5. Expand an existing UESWL service means the addition of one UESWL unit at an existing UESWL service. An applicant proposing to expand an existing UESWL service, whether fixed or mobile, unless otherwise specified, shall demonstrate the following:
- (1) All of the applicant's existing UESWL units, both fixed and mobile, at the same geographic location as the proposed additional UESWL unit, have performed an average of at least 1,800 procedures per UESWL unit during the most recent 12-month period for which the Department has verifiable data. In computing this average, the Department will divide the total number of UESWL procedures performed by the applicant's total number of UESWL units, including both operational and approved but not operational fixed and mobile UESWL units.
- (2) The applicant shall project an average of at least 1,000 procedures for each existing and proposed fixed and mobile UESWL unit(s) as a result from the application of the methodology in Section 10 of these standards for the second 12-month period after initiation of operation of each additional UESWL unit whether fixed or mobile.
- (3) An applicant proposing to expand an existing mobile UESWL service must provide a copy of the existing or revised contracts between the central service coordinator and each host site(s) that includes the same stipulations as specified in Section 7(1)(c).

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

- Sec. 6. Acquisition of an existing UESWL service or existing UESWL unit(s)" means obtaining possession or control of an existing fixed or mobile UESWL service or existing UESWL unit(s) by purchase, lease, donation, or other comparable arrangement.
- (1) An-THE applicant proposing to acquire an existing fixed or mobile UESWL service and its unit(s) shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs demonstrate that AIF THE proposed project meets all-ONE of the following:

- (a) For an application for the proposed IT IS THE first acquisition of an THE existing fixed or mobile UESWL service, for which a final decision has not been issued after May 2, 1998, an existing UESWL service to be acquired shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs. The UESWL service and its unit(s) shall be operating at the applicable volume requirements set forth in Section 9 of these standards in the second 12 months after the date the service and its unit(s) is acquired, and annually thereafter.
- (b) THE EXISTING FIXED OR MOBILE UESWL SERVICE IS OWNED BY, IS UNDER COMMON CONTROL OF, OR HAS A COMMON PARENT AS THE APPLICANT, AND THE UESWL SERVICE SHALL REMAIN AT THE SAME SITE.
- (2) For any application for proposed acquisition of an existing fixed or mobile UESWL service, except the first AN application approved pursuant to subsection (a1), for which a final decision has not been issued after May 2, 1998, an applicant shall be required to demonstrate that the UESWL service and its unit(s) to be acquired performed an average of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data.
- (23) An applicant proposing to acquire an existing fixed or mobile UESWL unit(S) of an existing UESWL service shall demonstrate that the proposed project meets all of the following:
- (a) For any application for proposed acquisition of an existing fixed or mobile UESWL unit(s), an applicant shall be required to demonstrate that the UESWL unit(s) to be acquired performed an average of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data.
  - (b) The requirements of Section 3(1)(c) have been met.
- (4) The UESWL service and its unit(s) shall be operating at the applicable volume requirements set forth in Section 9 of these standards in the second 12 months after the date the service and its unit(s) is acquired, and annually thereafter.

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

- Sec. 7. (1) An applicant proposing to begin operation of a mobile UESWL service in Michigan shall demonstrate that it meets all of the following:
- (a) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposing to operate when the results of the methodology in Section 10 are combined for the following, as applicable:
- (i) All licensed hospital sites committing MIDB data pursuant to Section 11, as applicable, that are located in the region identified in subsection (b).
- (ii) All sites that receive UESWL services from an existing UESWL unit and propose to receive UESWL services from the proposed mobile unit are located in the region(s) identified in subsection (b).
- (b) The normal route schedule, the procedures for handling emergency situations, and copies of all potential contracts related to the mobile UESWL service and its unit(s) shall be included in the CON application submitted by the central service coordinator.
- (2) The requirements of sections 3, 4, and subsection (1)(a) shall not apply to an applicant that proposes to add a Michigan site as a host site if the applicant demonstrates that the mobile UESWL service and its unit(s) operates predominantly outside of Michigan and all of the following requirements are met:
  - (a) The proposed host site is located in a rural or micropolitan statistical area county.
- (b) All existing and approved Michigan UESWL service and its unit(s) locations (whether fixed or mobile) are in excess of 50 miles from the proposed host site and within a region currently served by a UESWL mobile service operating predominantly outside of Michigan.
  - (c) A separate CON application has been submitted by the CSC and each proposed host site.

- (3) A central service coordinator proposing to add, or an applicant proposing to become, a host site on either an existing or a proposed mobile UESWL service shall demonstrate that it meets the requirements of Section 3(1)(C).
- (4) A central service coordinator proposing to add, or an applicant proposing to become, a host site on an existing mobile UESWL service in a region not currently served by that service shall demonstrate that at least 100 UESWL procedures are projected in each region in which the existing mobile UESWL service is proposing to add a host site when the results of the methodology in Section 10 are combined for the following, as applicable:
- (a) All licensed hospital sites committing MIDB data pursuant to Section 11, as applicable, are located in that region(s).
- (b) All sites that receive UESWL services from an existing UESWL service and its unit(s) and propose to receive UESWL services from the proposed mobile service and its unit(s) are located in that region(s).

# Section 8. Requirements for Medicaid participation

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

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

- Sec 9. An applicant shall agree that, if approved, UESWL services, including all existing and approved UESWL units, shall be delivered in compliance with the following:
  - (1) Compliance with these standards.
  - (2) Compliance with the following quality assurance standards:
- (a) The medical staff and governing body shall receive and review at least annual reports describing activities of the UESWL service, including complication rates, morbidity data, and retreatment rates.
- (b) An applicant shall accept referrals for UESWL services from all appropriately licensed health care practitioners.
- (c) An applicant shall develop and utilize a standing medical staff and governing body rule that provides for the medical and administrative control of the ordering and utilization of UESWL services.
- (d) An applicant shall require that each urologist serving as a UESWL surgeon shall have completed an approved training program in the use of the lithotripter at an established facility with UESWL services.
- (e) An applicant shall establish a process for credentialing urologists who are authorized to perform UESWL procedures at the applicant facility. This shall not be construed as a requirement to establish specific credentialing requirements for any particular hospital or UESWL site.
- (f) A urologist who is not an active medical staff member of an applicant facility shall be eligible to apply for limited staff privileges to perform UESWL procedures. Upon request by the Department, an applicant shall provide documentation of its process that will allow a urologist who is not an active medical staff member to apply for medical staff privileges for the sole and limited purpose of performing UESWL procedures. In order to be granted staff privileges limited to UESWL procedures, a urologist shall demonstrate that he or she meets the same requirements, established pursuant to the provisions of subsection (e), that a urologist on an applicant facility's active medical staff must meet in order to perform UESWL procedures.
- (g) An applicant shall provide UESWL program access to approved physician residency programs for teaching purposes.
  - (3) Compliance with the following access to care requirements:
  - (a) An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:
  - (i) Not deny any UESWL services to any individual based on inability to pay or source of payment,

services, and

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- (ii) Provide all UESWL services to any individual based on clinical indications of need for the
- (iii) Maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.
- (b) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.
- (c) The operation of and referral of patients to the UESWL service shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

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

- (4) Compliance with the following monitoring and reporting requirements:
- (a) Each UESWL unit, whether fixed or mobile, shall perform at least an average of 1,000 procedures per unit per year in the second 12 months of operation and annually thereafter. The central service coordinator shall demonstrate that a mobile UESWL unit approved pursuant to these standards performed at least 100 procedures in each region that is served by the mobile unit. For purposes of this requirement, the number of UESWL procedures performed at all host sites in the same region shall be combined.
- (b) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information; operating schedules; and demographic, diagnostic, morbidity and mortality information; primary diagnosis code; whether the procedure was a first or retreatment UESWL procedure; what other treatment already has occurred; outpatient or inpatient status; complications; and whether follow-up procedures (e.g., percutaneous nephrotomy) were required, as well as the volume of care provided to patients from all payor sources. An applicant shall provide the required data on a separate basis for each host site or licensed site in a format established by the Department and in a mutually-agreed-upon media. The Department may elect to verify the data through on-site review of appropriate records.
- (c) The applicant shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.
  - (5) Compliance with the following mobile UESWL requirements, if applicable:
- (a) The volume of UESWL procedures performed at each host site shall be reported to the Department by the central service coordinator.
- (b) An applicant with an approved CON for a mobile UESWL service shall notify the Department and the local CON review agency, if any, at least 30 days prior to dropping an existing host site.
- (c) Each mobile UESWL service shall establish and maintain an Operations Committee consisting of the central service coordinator's medical director and members representing each host site and the central service coordinator. This committee shall oversee the effective and efficient use of the UESWL unit, establish the normal route schedule, identify the process by which changes are to be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile UESWL service and its unit(s) on at least a quarterly basis.
- (d) The central service coordinator shall arrange for emergency repair services to be available 24 hours each day for the mobile UESWL unit equipment and the vehicle transporting the equipment.
- (e) If the host site will not be performing the lithotripsy procedures inside the facility, it must provide a properly prepared parking pad for the mobile UESWL unit of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host site also must provide the capability for maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host site to provide for immediate notification of emergency medical situations.
- (f) A mobile UESWL service shall operate under a contractual agreement that includes the provision of UESWL services at each host site on a regularly scheduled basis.
- (6) The agreements and assurances required by this Section shall be in the form of a certification agreed to by the applicant or its authorized agent.

#### Section 10. Methodology for projecting UESWL procedures

- Sec. 10. (1) The methodology set forth in this subsection shall be used for projecting the number of UESWL procedures at a site or sites that do not provide UESWL services as of the date an application is submitted to the Department. In applying the methodology, actual inpatient discharge data, as specified in the most recent Michigan Inpatient Database available to the Department on the date an application is deemed complete shall be used for each licensed hospital site for which a signed data commitment form has been provided to the Department in accordance with the provisions of Section 11. In applying inpatient discharge data in the methodology, each inpatient record shall be used only once and the following steps shall be taken in sequence:
- (a) The number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM codes 592.0, 592.1, or 592.9 (see Appendix D for ICD-10-CM Codes) shall be counted.
- (b) The result of subsection (a) shall be multiplied by the factor specified in Appendix A for each licensed hospital site that is committing its inpatient discharge data to a CON application. If more than one licensed hospital site is committing inpatient discharge data in support of a CON application, the products from the application of the methodology for each licensed hospital site shall be summed.
- (c) The result of subsection (b) is the total number of projected UESWL procedures for an application that is proposing to provide fixed or mobile UESWL services at a site, or sites in the case of a mobile service, that does not provide UESWL service, either fixed or mobile, as of the date an application is submitted to the Department.
- (2) For a site or sites that provide UESWL services as of the date an application is submitted to the Department, the actual number of UESWL procedures performed at each site, during the most recent continuous 12-month period for which the Department has verifiable data, shall be the number used to project the number of UESWL procedures that will be performed at that site or sites.
- (3) For a proposed UESWL unit, except for initiation, the results of subsections (1) and (2), as applicable, shall be summed and the result is the projected number of UESWL procedures for the proposed UESWL unit for purposes of the applicable sections of these standards.
- (4) An applicant that is projecting UESWL procedures pursuant to subsection (1) shall provide access to verifiable hospital-specific data and documentation using a format prescribed by the Department.

# Section 11. Requirements for MIDB data commitments

- Sec. 11. (1) In order to use MIDB data in support of an application for UESWL services, an applicant shall demonstrate or agree to, as applicable, all of the following.
- (a) A licensed hospital site whose MIDB data is used in support of a CON application for a UESWL service shall not use any of its MIDB data in support of any other application for a UESWL service for 5 years following the date the UESWL service to which the MIDB data are committed begins to operate. The licensed hospital site shall be required to commit 100% of its inpatient discharge data to a CON application.
- (b) The licensed hospital site, or sites, committing MIDB data to a CON application has completed the departmental form(s) that agrees to or authorizes each of the following:
  - (i) The Michigan Health and Hospital Association may verify the MIDB data for the Department.
  - (ii) An applicant shall pay all charges associated with verifying the MIDB data.
- (iii) The commitment of the MIDB data remains in effect for the period of time specified in subsection (1)(a).
- (c) A licensed hospital site that is proposing to commit MIDB data to an application is admitting patients regularly as of the date the director makes the final decision on that application under Section 22231(9) of the Code, being Section 333.22231(9) of the Michigan Compiled Laws.
- (2) The Department shall consider an MIDB data commitment in support of an application for a UESWL service from a licensed hospital site that meets all of the following:

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- (a) The licensed hospital site proposing to commit MIDB data to an application does not provide, or does not have a valid CON to provide, UESWL services, either fixed or mobile, as of the date an application is submitted to the Department.
- (b) The licensed hospital site proposing to commit MIDB data is located in a region in which a proposed fixed UESWL service is proposed to be located or, in the case of a mobile unit, has at least one host site proposed in that region.
  - (c) The licensed hospital site meets the requirements of subsection (1), as applicable.

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

- Sec. 12. (1) These CON review standards supersede and replace the CON review standards for urinary extracorporeal shock wave lithotripsy (UESWL) services approved by the CON Commission on March 18SEPTEMBER 25, 2014 and effective on June DECEMBER 22, 2014.
  - (2) Projects reviewed under these standards shall not be subject to comparative review.

APPENDIX A

## **Factor For Calculating Projected UESWL Procedures**

- (1) Until changed by the Department, the factor to be used in Section 10(1)(b) used for calculating the projected number of UESWL procedures shall be 1.09104.
- (2) The Department may amend Appendix A by revising the factor in subsection (1) in accordance with the following steps:
  - (a) Steps for determining statewide UESWL adjustment factor:
- (i) Determine the total statewide number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM codes 592.0, 592.1, or 592.9 (see Appendix D for ICD-10-CM Codes) for the most recent year for which Michigan Inpatient Database information is available to the Department.
- (ii) Determine the total number of UESWL procedures performed in the state using the Department's Annual Hospital Questionnaire for the same year as the MIDB being used in subsection (i) above.
- (iii) Divide the number of UESWL procedures determined in subsection (ii) above by the number of inpatient records determined in subsection (i) above.
  - (b) Steps for determining "urban/rural" adjustment factor:
- (i) For each hospital, assign urban/rural status based on the 2000 census COUNTY CLASSIFICATIONS FOUND IN APPENDIX C. "Metropolitan statistical area counties" will be assigned "urban" status, and "micropolitan statistical area" and "rural" counties will be assigned "rural" status.
  - (ii) Aggregate the records from step (a)(i) by zip code "urban/rural" status.
- (iii) Identify the zip codes in which all records are either "urban" status or "rural" status. Aggregate the number of records and zip code populations separately by "urban/rural" status.
- (iv) For zip codes having records in both "urban" and "rural" status, Calculate the proportion of records in "urban" and "rural" by dividing the respective number of records by the total number of records for that zip code. Multiply the population of each zip code by its respective "urban" and "rural" proportions.
  - (v) Aggregate the records and populations from step (b)(iv) separately by "urban/rural" status.
- (vi) The sub-totals from step (v) will then be added to the sub-totals from step (iii) to produce totals for "urban" & "rural" separately. Calculate the "urban" and "rural" discharge rates per 10,000 (DRU and DRR, respectively) by dividing the total number of records by the total population for each status, then multiplying by 10,000.
- (vii) Divide the urban discharge rate by the rural discharge rate (DRU/DRR) to calculate the "urban/rural" adjustment factor. Multiply the statewide adjustment factor identified in step (a)(iii) by the "urban/rural" adjustment factor. The result is the revised factor for calculating UESWL procedures.
- (3) The Department shall notify the Commission when this revision is made and the effective date of the revision.

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492	Carratia		ian ara aa fallawa.		
493 494	Countie	es assigned to each reg	ion are as follows:		
494	Region	Counties			
496					
497	1	Livingston	Monroe	Macomb	Oakland
498		St. Clair	Washtenaw	Wayne	
499				•	
500	2	Clinton	Eaton	Hillsdale	Ingham
501		Jackson	Lenawee		
502					
503	3	Barry	Berrien	Branch	Calhoun
504		Cass	Kalamazoo	St. Joseph	Van Buren
505		A 11		14	
506	4	Allegan	Ionia	Kent	Lake
507		Mason	Mecosta	Montcalm	Muskegon
508		Newaygo	Oceana	Osceola	Ottawa
509 510	5	Genesee	Lancar	Shiawassee	
510	5	Genesee	Lapeer	Sillawassee	
511	6	Arenac	Bay	Clare	Gladwin
513	U	Gratiot	Huron	losco	Isabella
514		Midland	Ogemaw	Roscommon	Saginaw
515		Sanilac	Tuscola	110000111111011	Caginaw
516			. 3333.6		
517	7	Alcona	Alpena	Antrim	Benzie
518		Crawford	Charlevoix	Cheboygan	Emmet
519		Gd. Traverse	Kalkaska	Leelanau	Manistee
520		Missaukee	Montmorency	Oscoda	Otsego
521		Presque Isle	Wexford		-
522					
523	8	Alger	Baraga	Chippewa	Delta
524		Dickinson	Gogebic	Houghton	Iron
525		Keweenaw	Luce	Mackinac	Marquette
526		Menominee	Ontonagon	Schoolcraft	
527					

528				APPENDIX C
529	Pural Michigan counting are as	follows		
530 531	Rural Michigan counties are as follows:			
532	Alcona	Gogebic	Ogemaw	
533	Alger	Huron	Ontonagon	
534	Antrim		Osceola	
		losco	Osceola	
535	Arenac	Iron		
536	Baraga	Lake	Otsego	
537	Charlevoix	Luce	Presque Isle	
538	Cheboygan	Mackinac	Roscommon	
539	Clare	Manistee	Sanilac	
540	Crawford	Montmorency	Schoolcraft	
541	Emmet	Newaygo	Tuscola	
542	Gladwin	Oceana		
543				
544	Micropolitan statistical area Mic	higan counties are as follows:		
545				
546	Allegan	Hillsdale	Mason	
547	Alpena	Houghton	Mecosta	
548	Benzie	Ionia	Menominee	
549	Branch	Isabella	Missaukee	
550	Chippewa	Kalkaska	St. Joseph	
551	Delta	Keweenaw	Shiawassee	
552	Dickinson	Leelanau	Wexford	
553	Grand Traverse	Lenawee		
554	Gratiot	Marquett		
555				
556	Metropolitan statistical area Michigan counties are as follows:			
557				
558	Barry	Jackson	Muskegon	
559	Bay	Kalamazoo	Oakland	
560	Berrien	Kent	Ottawa	
561	Calhoun	Lapeer	Saginaw	
562	Cass	Livingston	St. Clair	
563	Clinton	Macomb	Van Buren	
564	Eaton	Midland	Washtenaw	
565	Genesee	Monroe	Wayne	
566	Ingham	Montcalm		
567				
568	Source:			
569				
570	75 F.R., p. 37245 (June 28, 201	0)		
571	Statistical Policy Office	,		
572	Office of Information and Regula	atory Affairs		
573	United States Office of Manager			
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# **APPENDIX D**

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

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
592.0	Calculus of	N20.0	Calculus of Kidney
	Kidney	N20.2	Calculus of Kidney with Calculus of Ureter
	Calculus of	N20.1	Calculus of Ureter
	Ureter	N20.2	Calculus Of Kidney with Calculus of Ureter
	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 <u>International Classification of Diseases - 9th Revision - Clinical Modification</u>, 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 <u>International Classification</u> <u>Of Diseases - 10th Revision - Clinical Modification</u>, National Center for Health Statistics.

# FINAL REPORT AND RECOMMENDATIONS

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

To: CON Commission

From: Marianne Conner, CPA

CON NH HLTCU Workgroup Chair

Date: March 16, 2017 CON Commission meeting

**RE: CON NH HLTCU Workgroup final report and recommendations** 

The CON NH HLTCU Workgroup met a total of seven times: July 21, 2016, August 17, 2016, October 13, 2016, November 10, 2016, December 15, 2016, and February 9, 2017

The Workgroup was given eight charges to consider. A sub-group was formed to work on Charges 3 and 4 dealing with Special Populations and High Occupancy. The recommendations of this sub-group were presented at our November 10<sup>th</sup> and agreed to at our December 15<sup>th</sup> meeting by all present. That decision is included in our overall recommendations.

There was excellent participation and discussion in regards to all of the charges given to the workgroup. I am especially grateful for the assistance of Brenda, Beth, Tulika, and Joette from the Department, in providing feedback on not only the workgroup process but how CON practically functions. The participation offered by the State Ombudsman, the provider associations, consultants, and provider representatives gave the group a broad perspective on each of the issues. I learned a tremendous amount about the CON standards by serving on this workgroup, for which I thank all of you.

**CON NH HLTCU Workgroup recommendations and rationales:** Please refer to the Proposed CON Revised Standards from 3/16/2017 edits as highlighted for specific recommended wording.

# Charge 1: Review the criteria for NH-HLTCU replacements and relocation of beds.

The workgroup wording clarifies that replacements and relocations of beds is not subject to comparative review under the following circumstances as defined in Section 14.

#### Section 14

Proposed 14(2): Projects reviewed under these standards involving a change in bed capacity shall be subject to comparative review except as follows: (a) replacement of an existing nursing home/HLTCU being replaced in THE REPLACEMENT ZONE; (b) replacement of an existing nursing home/HLTCU PURSUANT TO SECTION 7(3) AND WITHIN THE SAME PLANNING AREA AS THE EXISTING LICENSED SITE.

Rationale: This wording clarifies that replacements and relocations within the replacement zone and/or under Section 7(3) are not subject to comparative review eliminating confusion in this area. This eliminates the date constraints for filing under comparative review criteria for these projects.

#### Charge 2: Review the criteria concerning lease renewals

The workgroup reviewed Section 9(3) on renewal of leases to determine if there were ways to relieve the financial burden on the providers of these CON applications while maintaining the Department's desire to review these projects to determine if they still meet current standards. After much discussion and an interpretation from the Attorney General's office on capital projects and the workgroup agreed to not recommend any changes to the current standards at this time. Some members of the workgroup mentioned that they may seek other venues to change the inclusion of lease renewals within CON.

## Charge 3: Review the threshold for high occupancy provisions

A sub-group of the workgroup worked on the issues involved in determining today's high occupancy standard and compared to standards provided for other healthcare entities. The recommendations take into account the shorter length of stay nationwide in skilled nursing facilities while requiring dual certification of the high occupancy beds, and the elimination of any wards in existence at an applicant facility.

#### Section 6

Proposed 6(1)(d)(ii) An applicant may request and be approved for up to a maximum of 20 beds if the following requirements ae met:

- (A) The applicant facility has experienced an average occupancy rate of 92% FOR THE MOST RECENT 12 CONSECUTIVE MONTHS AND 90% OR ABOVE FOR THE PRIOR 2 MONTHS AS VERIFIABLE BY THE DEPARTMENT AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT
- (B) THE APPLICANT FACILITY HAS NOT DECREASED THE NUMBER OF LICENSED BEDS WITHIN THE 24 MONTHS PRECEDING THE APPLICATION DATE.
- (C) THE APPLICANT FACILITY SHALL PROPOSE NO MORE THAN TWO BEDS PER RESIDENT ROOM AND SHALL ELIMINATE ALL THREE AND/OR FOUR BED WARDS WITHIN THE EXISTING FACILITY, IF APPLICABLE, AS PART OF THE PROPOSED PROJECT.
- (D) THE APPLICANT FACILITY SHALL CERTIFY THE NEW BEDS FOR BOTH MEDICARE AND MEDICAID.
- (E) THE APPLICANT FACILITY SHALL NOT RELOCATE ANY BEDS FROM THE FACILITY OR REPLACE A PORTION OF BEDS TO A NEW SITE PURSUANT TO SECTION 7(3)(D), FOLLOWING CON APPROVAL AND FOR AT LEAST 24 MONTHS FROM THE DATE OF THE LICENSURE OF THE NEW BEDS AT THE FACILITY.

Existing 6(1)(d)(ii) An exception to the number of beds may be approved, if the applicant facility has experienced an average occupancy rate of 97% for three years based on the CON Annual Survey. The number of beds that may be approved in excess of the bed need for each planning area is set forth in subsection (A).

(A) The number of beds that may be approved pursuant to this subsection shall be the number of beds necessary to reduce the occupancy rate for the planning area in which the additional beds are proposed to the ADC adjustment factor for that planning area as shown in Appendix C. The number of beds shall be calculated by (1) dividing the actual number of patient days of care provided during the most recent 12-month period for which verifiable data are available to the Department provided by all nursing home (including HLTCU) beds in the planning area, including patient days of care provided in beds approved from the statewide pool of beds and dividing that result by 365 (or 366 for leap years); (2) dividing the result of step (1) by the ADC adjustment factor for the planning area in which the beds are proposed to be added; (3) rounding the result of step (2) up to the next whole number; and (4) subtracting the total number of beds in the planning area including beds approved from the statewide pool of beds

from the result of step (3). If the number of beds necessary to reduce the planning area occupancy rate to the ADC adjustment factor for that planning area is equal to or more than 20, the number of beds that may be approved pursuant to this subsection shall be up to that number of beds. If the number of beds necessary to reduce the planning area occupancy rate to the ADC adjustment factor for that planning area is less than 20, the number of additional beds that may be approved shall be that number of beds or up to a maximum of 20 beds.

Updates are also made at Section 7(3)(d) and Section 8(1)(f) for consistency on the relocation of beds.

Rationale: A facility operating at 92% occupancy is a high occupancy facility in this environment of shorter lengths of stay and managed care. Facilities maintaining this level of occupancy that wish to expand should have the opportunity regardless of the overall occupancy of the county in which they are located.

# Charge 4: Review the special population groups in the addendum

A subgroup of the workgroup evaluated the current special population groups and determined a current need exists to create additional designated bariatric rooms for a growing long term care population group.

# Addendum for Special Population Groups

#### Section 1

- 4(a) BARIATRIC PATIENT MEANS A PATIENT WEIGHING OVER 350 POUNDS.
- 4(b) BARIATRIC ROOM MEANS THE CREATION OF PATIENT ROOM(S) INCLUDED AS PART OF THE CON PROJECT, AND IDENTIFIED ON THE ARCHITECTURAL SCHEMATICS, THAT ARE DESIGNED TO ACCOMMODATE THE NEEDS OF BARIATRIC PATIENTS WEIGHING OVER 350 POUNDS. THE BARIATRIC PATIENT ROOMS SHALL HAVE A LARGER ENTRANCE WIDTH FOR THE ROOM AND BATHROOM TO ACCOMMODATE OVER-SIZED EQUIPMENT, AND SHALL INCLUDE A MINIMUM OF A BARIATRIC BED, BARIATRIC TOILET, BARIATRIC WHEELCHAIR, AND A DEVICE TO ASSIST RESIDENT MOVEMENT (SUCH AS A PORTABLE OR BUILT IN LIFT). IF AN IN-ROOM SHOWER IS NOT INCLUDED IN THE BARIATRIC PATIENT ROOM, THE MAIN/CENTRAL SHOWER ROOM THAT IS LOCATED ON THE SAME FLOOR AS THE BARIATRIC PATIENT ROOM(S) SHALL INCLUDE AT LEAST ONE (1) SHOWER STALL THAT HAS AN OPENING WIDTH AND DEPTH THAT IS LARGER THAN MINIMUM MI CODE REQUIREMENTS.

# Section 3

3(1)(a)(iii) BARIATRIC beds will be allocated 60 beds.

3(1)(b)(iv) Hospice beds has 70 beds.

#### Section 6

Section 6. Requirements for approval for beds from the statewide pool for special population groups allocated to BARIATRIC 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 BARIATRIC PATIENTS AS COMPARED TO SERVING THESE NEEDS IN GENERAL NURSING HOME UNIT(S).

- (1) An applicant proposing to begin operation of a new nursing home/HLTCU or add beds to an existing nursing home/HLTCU under this section shall demonstrate, with credible documentation to the satisfaction of the Department, each of the following:
- (a) THE FACILITY SHALL NOT BE AWARDED MORE THAN 10 BEDS.
- (b) THE FACILITY MAY PLACE BEDS THROUGHOUT THE FACILITY FOR A FLEXIBLE AND SEAMLESS INCLUSIVE RESIDENT DESIGN.
- (c) THE PROPOSED BEDS SHALL HAVE ADEQUATE ACCESS TO AN OUTDOOR OR INDOOR AREA FOR ACTIVITIES WITH APPROPRIATE EQUIPMENT.
- (d) THE PHYSICAL ENVIRONMENT OF ANY UNIT CONTAINING BARIATRIC BEDS SHALL BE DESIGNED TO FACILITATE VISITORS.
- (e) THE UNIT/BEDS SHALL HAVE AVAILABLE SPECIALTY EQUIPMENT TO ASSIST STAFF IN PROVIDING CARE.
- (f) THE BEDS SHALL BE LOCATED ON A GROUND FLOOR AND EMERGENCY EGRESS WILL NOT REQUIRE STAIRWAYS OR ELEVATORS TO EXIT.
- (g) THE BEDS SHALL BE ESTABLISHED IN EITHER SINGLE OR DOUBLE OCCUPANCY ROOMS, THERE SHALL BE NO ROOMS WITH MORE THAN TWO BEDS.
- (2) BEDS APPROVED UNDER THIS SUBSECTION SHALL NOT BE CONVERTED TO OR UTILIZED FOR GENERAL NURSING HOME USE WITHOUT A CON FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS.
- (3) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

#### Section 8

- 8(6) AN APPLICANT PROPOSING TO ACQUIRE NURSING HOME/HLTCU BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO BARIATRIC PATIENTS SHALL MEET THE FOLLOWING:
- (a) THE FACILITY SHALL NOT BE AWARDED MORE THAN 10 BEDS.
- (b) THE FACILITY MAY PLACE BEDS THROUGHOUT THE FACILITY FOR A FLEXIBLE AND SEAMLESS INCLUSIVE RESIDENT DESIGN.
- (c) THE PROPOSED BEDS SHALL HAVE ADEQUATE ACCESS TO AN OUTDOOR OR INDOOR AREA FOR ACTIVITIES WITH APPROPRIATE EQUIPMENT.
- (d) THE PHYSICAL 1621 ENVIRONMENT OF ANY UNIT CONTAINING BARIATRIC BEDS SHALL BE DESIGNED TO FACILITATE VISITORS.
- (e) THE BEDS SHALL HAVE AVAILABLE SPECIALTY EQUIPMENT TO ASSIST STAFF IN PROVIDING CARE.
- (f) THE BEDS SHALL BE LOCATED ON A GROUND FLOOR AND EMERGENCY EGRESS WILL NOT REQUIRE STAIRWAYS OR ELEVATORS TO EXIT.
- (g) BEDS APPROVED UNDER THIS SUBSECTION SHALL NOT BE CONVERTED TO OR UTILIZED AS GENERAL NURSING HOME USE WITHOUT A CON FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS UNDER THE CON REVIEW STANDARDS.
- (i) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

# Section 9

- 9(8) AN APPLICANT FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO BARIATRIC PATIENTS SHALL AGREE THAT IF APPROVED:
- (a) THE FACILITY SHALL NOT BE AWARDED MORE THAN 10 BEDS.

- (b) THE FACILITY MAY PLACE BEDS THROUGHOUT THE FACILITY FOR A FLEXIBLE AND SEAMLESS INCLUSIVE RESIDENT DESIGN.
- (c) THE PROPOSED BEDS SHALL HAVE ADEQUATE ACCESS TO AN OUTDOOR OR INDOOR AREA FOR ACTIVITIES WITH APPROPRIATE EQUIPMENT.
- (d) THE PHYSICAL ENVIRONMENT OF ANY UNIT CONTAINING BARIATRIC BEDS SHALL BE DESIGNED TO FACILITATE VISITORS.
- (e) THE BEDS SHALL HAVE AVAILABLE SPECIALTY EQUIPMENT TO ASSIST STAFF IN PROVIDING CARE.
- (f) THE BEDS SHALL BE LOCATED ON A GROUND FLOOR AND EMERGENCY EGRESS WILL NOT REQUIRE STAIRWAYS OR ELEVATORS TO EXIT.
- (g) THE BEDS SHALL BE ESTABLISHED IN EITHER SINGLE OR DOUBLE OCCUPANCY ROOMS, THERE SHALL BE NO ROOMS WITH MORE THAN TWO BEDS.
- (i) ALL BEDS APPROVED PURSUANT TO THIS SUBSECTION SHALL BE DUALLY CERTIFIED FOR MEDICARE AND MEDICAID.

Rationale: There is a need for more bariatric specific beds in the State and this may encourage providers to provide these special population rooms.

#### Charge 5: Review the bed need formula and data sources

The workgroup discussed Dr. Delamater's methodology and the issues related to incorrect and late data being provided by providers. The workgroup overall had no changes to the methodology other than to seek consistency in the ADC adjustment factor. Currently, there are two categories, ADC of less than 100 and those at 100 or more. The adjustment factor is currently .90 for less than 100 ADC, and .95 for 100 or more ADC. The group recommends that the factor be the same for all locations.

# Section 2

2(b) "ADC adjustment factor" means the factor by which the average daily census (ADC), derived during the bed need methodology calculation set forth in Section 3(2)(d) for each planning area, is divided. The ADC adjustment factor is 0.90 for ALL planning areas.

#### Section 3

3(2)(e) Divide the ADC DETERMINED IN SUBSECTION (d) by 0.90.

Rationale: The ADC adjustment should be calculated consistently throughout the State and reflect the overall change in occupancy and lengths of stay.

# Charge 6: Review quality metrics to determine if they are up-to-date with national NH-HLTCU trends.

The workgroup reviewed Section 9(1)(f) at the request of the Department to determine if there were further guidance as to the specific quality improvement program an applicant should participate in if needed. The workgroup determine there are currently limited options and feel it should be left to the discretion of the Department. The Workgroup recommends no changes be made to this section of the standards.

Charge 7: Revise acquisition requirements to reflect a situation where the NH-HLTCU is being acquired by a new entity that does not currently operate a NH-HLTCU.

The Department requested the workgroup assist in reviewing new language in this area that would assist them in processing applications from new providers.

#### Section 9

- 9(1)(g) IF THE APPLICANT IS A NEW ENTITY WITH NO PRIOR NH-HLTCU HISTORY, THE APPLICANT SHALL SUBMIT PROOF THAT:
- (i) THE NURSING HOME/HLTCU TO BE ACQUIRED IS NO LONGER LISTED AS A SPECIAL FOCUS NURSING HOME BY THE CENTER FOR MEDICARE AND MEDICAID SERVICES, OR THE APPLICANT SHALL PARTICIPATE IN A QUALITY IMPROVEMENT PROGRAM, APPROVED BY THE DEPARTMENT, FOR FIVE YEARS AND PROVIDE AN ANNUAL REPORT TO THE MICHIGAN STATE LONG-TERM-CARE OMBUDSMAN, BUREAU OF HEALTH CARE SERVICES WITHIN LARA, AND SHALL POST THE ANNUAL REPORT IN THE FACILITY; AND
- (ii) ALL DELINQUENT DEBT OBLIGATIONS TO THE STATE OF MICHIGAN INCLUDING, BUT NOT LIMITED TO, QAAP, PASARR OR CMPs HAVE BEEN PAID.
- 9(2)(e) IF THE APPLICANT IS A NEW ENTITY WITH NO PRIOR NH-HLTCU HISTORY, THE APPLICANT SHALL SUBMIT PROOF THAT:
- (i) THE NURSING HOME/HLTCU TO BE ACQUIRED IS NO LONGER LISTED AS A SPECIAL FOCUS NURSING HOME BY THE CENTER FOR MEDICARE AND MEDICAID SERVICES, OR THE APPLICANT SHALL PARTICIPATE IN A QUALITY IMPROVEMENT PROGRAM, APPROVED BY THE DEPARTMENT, FOR FIVE YEARS AND PROVIDE AN ANNUAL REPORT TO THE MICHIGAN STATE LONG-TERM-CARE OMBUDSMAN, BUREAU OF HEALTH CARE SERVICES WITHIN LARA, AND SHALL POST THE ANNUAL REPORT IN THE FACILITY; AND
- (ii) ALL DELINQUENT DEBT OBLIGATIONS TO THE STATE OF MICHIGAN INCLUDING, BUT NOT LIMITED TO, QAAP, PASARR OR CMPs HAVE BEEN PAID.

Rationale: The workgroup finds these recommendations from the Department to be reasonable for new providers in the State.

# **Charge 8: Technical changes from the Department**

The Department made numerous changes to the standards for updates including the change in name to Michigan Department of Health and Human Services and for updates in the Public Health Service Act. They also included references to the State of Michigan CON website for reference to eliminate the future need to make these changes.

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MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

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# CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT (HLTCU) BEDS

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

#### Section 1. Applicability

- Sec. 1. (1) These standards are requirements for approval under Part 222 of the Code that involve a) beginning operation of a new nursing home/HLTCU, (b) replacing beds in a nursing home/HLTCU or physically relocating nursing home/HLTCU beds from one licensed site to another geographic location, (c) increasing licensed beds in a nursing home/HLTCU licensed under Part 217 and a HLTCU defined in Section 20106(6), or (d) acquiring a nursing home/HLTCU. Pursuant to the Code, a nursing home/HLTCU 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 nursing home/HLTCU beds is a change in bed capacity for purposes of Part 222 of the Code.
- (3) The physical relocation of nursing home/HLTCU 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) As used in these standards:
- (a) "Acquisition of an existing nursing home/HLTCU" means the issuance of a new nursing home/HLTCU license as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing licensed and operating nursing home/HLTCU and which does not involve a change in bed capacity of that health facility.
- (b) "ADC adjustment factor" means the factor by which the average daily census (ADC), derived during the bed need methodology calculation set forth in Section 3(2)(d) for each planning area, is divided. The ADC adjustment factor is 0.90 for ALL planning areas.
- (c) "Applicant's cash" means the total unrestricted cash, designated funds, and restricted funds reported by the applicant as the source of funds in the application. If the project includes space lease costs, the applicant's cash includes the contribution designated for the project from the landlord.
- (d) "Base year" means 1987 or the most recent year for which verifiable data collected as part of the Michigan Department of Health AND HUMAN SERVICES Annual Survey of Long-Term-Care Facilities or other comparable MDHHS survey instrument are available.
- (e) "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.
- (f) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 <u>et seq.</u> of the Michigan Compiled Laws.
- (g) "Common ownership or control" means a nursing home, regardless of the state in which it is located, that is owned by, is under common control of, or has a common parent as the applicant nursing home pursuant to the definition of common ownership or control utilized by the Department of Licensing and Regulatory Affairs (LARA), Bureau of Health Care Services.

CON Review Standards for Nursing Home and HLTCU Beds For Proposed Action 3-16-17 Commission Meeting HIGHLIGHTED Text – Proposed edits CON-217

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- (h) "Comparative group" means the applications which have been grouped for the same type of project in the same planning area or statewide special pool group and which are being reviewed comparatively in accordance with the CON rules.
- (i) "Converted space" means existing space in a health facility that is not currently licensed as part of the nursing home/HLTCU and is proposed to be licensed as nursing home or HLTCU space. An example is proposing to license home for the aged space as nursing home space.
  - (j) "Department" means the Michigan Department of Health AND HUMAN SERVICES (MDHHS).
- (k) "Department inventory of beds" means the current list, for each planning area maintained on a continuing basis by the Department: (i) licensed nursing home beds and (ii) nursing home beds approved by a valid CON issued under Part 222 of the Code which are not yet licensed. It does not include (a) nursing home beds approved from the statewide pool and (b) short-term nursing care program beds approved pursuant to Section 22210 of the Code, being Section 333.22210 of the Michigan Compiled Laws.
- (I) "Existing nursing home beds" means, for a specific planning area, the total of all nursing home beds located within the planning area including: (i) licensed nursing home beds, (ii) nursing home beds approved by a valid CON issued under Part 222 of the Code which are not yet licensed, (iii) proposed nursing home beds under appeal from a final Department decision made under Part 222 or pending a hearing from a proposed decision issued under Part 222 of the Code, and (iv) proposed nursing home beds that are part of a completed application under Part 222 of the Code which is pending final Department decision. (a) Nursing home beds approved from the statewide pool are excluded; and (b) short-term nursing care program beds approved pursuant to Section 22210 of the Code, being Section 333.22210 of the Michigan Compiled Laws, are excluded.
- (m) "Health service area" or "HSA" means the geographic area established for a health systems agency pursuant to former Section 1511 of the Public Health Service Act and set forth in APPENDIX A.
- (n) "Hospital long-term-care unit" or "HLTCU" means a nursing care facility, owned and operated by and as part of a hospital, that provides organized nursing care and medical treatment to seven (7) or more unrelated individuals suffering or recovering from illness, injury, or infirmity.
- (o) "Licensed only facility" means a licensed nursing home that is not certified for Medicare or Medicaid.
- (p) "Licensed site" means the location of the health 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) "New design model" means a nursing home/HLTCU built in accordance with specified design requirements as identified in the applicable sections.
- (s) "Nursing home" means a nursing care facility, including a county medical care facility, but excluding a hospital or a facility created by Act No. 152 of the Public Acts of 1885, as amended, being sections 36.1 to 36.12 of the Michigan Compiled Laws, that provides organized nursing care and medical treatment to seven (7) or more unrelated individuals suffering or recovering from illness, injury, or infirmity. This term applies to the licensee only and not the real property owner if different than the licensee
- (t) "Nursing home bed" means a bed in a health facility licensed under Part 217 of the Code or a licensed bed in a hospital long-term-care unit. The term does not include short-term nursing care program beds approved pursuant to Section 22210 of the Code being Section 333.22210 of the Michigan Compiled Laws or beds in health facilities listed in Section 22205(2) of the Code, being Section 333.22205(2) of the Michigan Compiled Laws.
- (u) "Occupancy rate" means the percentage which expresses the ratio of the actual number of patient days of care provided divided by the total number of patient days. Total patient days is calculated by summing the number of licensed and/or CON approved but not yet licensed beds and multiplying these beds by the number of days that they were licensed and/or CON approved but not yet licensed. This shall include nursing home beds approved from the statewide pool. Occupancy rates shall be

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113 114 115 116 117 118 119 120 121 122 data are available. 123 124 125 126 127 128 129 130 131 132 133 134 135 donation, etc.) within the replacement zone. 136 137 138 licensed site. 139 140 141 142 143 144 per 1,000 population during a one-year period. 145 146 147 148 149 150 151 152 age 75 - 84 years, and (iv) age 85 and older. 153 154 155 in accord with subsection (1)(b), are POSTED ON THE STATE OF MICHIGAN CON WEB SITE. 156 157 158 159

calculated using verifiable data from the actual number of patient days of care for 12 continuous months of data from the CON Annual Survey or other comparable MDHHS survey instrument.

- (v) "Planning area" means the geographic boundaries of each county in Michigan with the exception of: (i) Houghton and Keweenaw counties, which are combined to form one planning area and (ii) Wayne County which is divided into three planning areas. Section 12 identifies the three planning areas in Wayne County and the specific geographic area included in each.
- (w) "Planning year" means 1990 or the year in the future, at least three (3) years but no more than seven (7) years, for which nursing home bed needs are developed. The planning year shall be a year for which official population projections, from the Department of Management and Budget or U.S. Census,
- (x) "Proposed licensed site" means the physical location and address (or legal description of property) of the proposed project or within 250 yards of the physical location and address (or legal description of property) and within the same planning area of the proposed project that will be authorized by license and will be listed on that licensee's certificate of licensure.
- (y) "Relocation of existing nursing home/HLTCU beds" means a change in the location of existing nursing home/HLTCU beds from the licensed site to a different existing licensed site within the planning
- (z) "Renewal of lease" means execution of a lease between the licensee and a real property owner in which the total lease costs exceed the capital expenditure threshold.
- (aa) "Replacement bed" means a change in the location of the licensed nursing home/HLTCU, the replacement of a portion of the licensed beds at the same licensed site, or the replacement of a portion of the licensed beds pursuant to the new model design. The nursing home/HLTCU beds will be in new physical plant space being developed in new construction or in newly acquired space (purchase, lease,
  - (bb) "Replacement zone" means a proposed licensed site that is.
  - (i) for a rural or micropolitan statistical area county, within the same planning area as the existing
    - (ii) for a county that is not a rural or micropolitan statistical area county,
    - (A) within the same planning area as the existing licensed site and
    - (B) within a three-mile radius of the existing licensed site.
- "Use rate" means the number of nursing home and hospital long-term-care unit days of care
  - (2) The definitions in Part 222 of the Code shall apply to these standards.

## Section 3. Determination of needed nursing home bed supply

Sec. 3 (1)(a) The age specific use rates for the planning year shall be the actual statewide age specific nursing home use rates using data from the base year.

- (b) The age cohorts for each planning area shall be: (i) age 0 64 years, (ii) age 65 74 years, (iii)
- (c) Until the base year is changed by the Commission in accord with Section 4(3) and Section 5, the use rates for the base year PER 1000 POPULATION for each corresponding age cohort, established
- (2) The number of nursing home 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 in the age cohorts established in subsection (1)(b).
- (b) Multiply each population age cohort by the corresponding use rate, WHICH IS POSTED ON THE STATE OF MICHIGAN CON WEB SITE.

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CON Review Standards for Nursing Home and HLTCU Beds For Proposed Action 3-16-17 Commission Meeting HIGHLIGHTED Text - Proposed edits

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- (c) Sum the patient days resulting from the calculations performed in subsection (b). The resultant figure is the total patient days.
- (d) Divide the total patient days obtained in subsection (c) by 365 (or 366 for leap years) to obtain the projected average daily census (ADC).
  - (e) Divide the ADC DETERMINED IN SUBSECTION (d) by 0.90.
- (f) The number determined in subsection (e) represents the number of nursing home beds needed in a planning area for the planning year.

#### Section 4. Bed need

- Sec. 4. (1) The bed need numbers shall apply to project applications subject to review under these standards, except where a specific CON standard states otherwise.
  - (2) The Department shall apply the bed need methodology in Section 3 on a biennial basis.
- (3) The base year and the planning year that shall be utilized in applying the methodology pursuant to subsection (2) shall be set according to the most recent data available to the Department.
  - (4) The effective date of the bed need numbers shall be established by the Commission.
- (5) New bed need numbers established by subsections (2) and (3) shall supersede previous bed need numbers and shall be posted on the state of Michigan CON web site as part of the Nursing Home/HLTCU Bed Inventory.
- (6) 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 age specific use rates by changing the base year

- Sec. 5. (1) The base year shall be modified based on data obtained from the Department and presented to the Commission. The Department shall calculate use rates for each of the age cohorts set forth in Section 3(1)(b) and biennially present the revised use rates based on 2006 information, or the most recent base year information available biennially after 2006, 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 increase beds in a planning area

- Sec. 6. An applicant proposing to increase the number of nursing home beds in a planning area must meet the following as applicable:
- (1) An applicant proposing to increase the number of nursing home beds in a planning area by beginning operation of a new nursing home/HLTCU or increasing the number of beds to an existing licensed nursing home/HLTCU shall demonstrate the following:

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(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing	All Michigan nursing homes/HLTCUs under
homes/HLTCUs	common ownership or control
Applicant with 10 or more Michigan nursing	All Michigan nursing homes/HLTCUs under
homes/HLTCUs and out of state nursing	common ownership or control
homes/HLTCUs	•
Applicant with fewer than 10 Michigan nursing	All Michigan and out of state nursing
homes/HLTCUs and out of state nursing	homes/HLTCUs under common ownership or
homes/HLTCUs	control

- (i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.
- (v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid
- (vi) Delinquent debt obligation to the State of Michigan including, but not limited to, Quality Assurance Assessment Program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or Civil Monetary Penalties (CMP).
- (b) The applicant certifies that the requirements found in the Minimum Design Standards for Health Care Facilities of Michigan, referenced in Section 20145 (6) of the Public Health Code, Act 368 of 1978, as amended and are published by the Department, will be met when the architectural blueprints are submitted for review and approval by the Department.
- (c) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.
- (d) The proposed increase, if approved, will not result in the total number of existing nursing home beds in that planning area exceeding the needed nursing home bed supply, unless one of the following is
- (i) An applicant may request and be approved for up to a maximum of 20 beds if, when the total number of "existing nursing home beds" is subtracted from the bed need for the planning area, the difference is equal to or more than 1 and equal to or less than 20. This subsection is not applicable to projects seeking approval for beds from the statewide pool of beds.
- (ii) An applicant may request and be approved for up to a maximum of 20 beds if the following requirements are met:

Deleted: An exception to the number of beds may be approved, if the applicant facility has experienced an av occupancy rate of 97% for three years based on the CON Annual Survey. The number of beds that may be approved in excess of the bed need for each planning area is set forth in subsection (A). ¶

. (A) The number of beds that may be approved pursuant to this subsection shall be the number of beds necessary to reduce the occupancy rate for the planning area in which the additional beds are proposed to the ADC adjustment factor for that planning area as shown in Appendix C. The number of beds shall be calculated by (1) dividing the actual number of patient days of care provided during the most recent 12-month period for which verifiable data are available to the Department provided by all nursing home (including HLTCU) beds in the planning area, including patient days of care provided in beds approved from the statewide pool of beds and dividing that result by 365 (or 366 for leap years); (2) dividing the result of step (1) by the ADC adjustment factor for the planning area in which the beds are proposed to be added; (3) rounding the result of step (2) up to the next whole number; and (4) subtracting the total number of beds in the planning area including beds approved from the statewide pool of beds from the result of step (3). If the number of beds necessary to reduce the planning area occupancy rate to the ADC adjustment factor for that planning area is equal to or more than 20, the number of beds that may be approved pursuant to this subsection shall be up to that number of beds If the number of beds necessary to reduce the planning area occupancy rate to the ADC adjustment factor for that planning area is less than 20, the number of additional beds that may be approved shall be that number of beds or up to a maximum of 20 beds.¶

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> CON Review Standards for Nursing Home and HLTCU Beds For Proposed Action 3-16-17 Commission Meeting HIGHLIGHTED Text - Proposed edits

(A) The applicant facility has experienced an average occupancy rate of 92% for the most recent 12 CONSECUTIVE MONTHS AND 90% OR ABOVE FOR THE PRIOR 12 MONTHS AS VERIFIABLE B THE DEPARTMENT AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT,

- (B) THE APPLICANT FACILITY HAS NOT DECREASED THE NUMBER OF LICENSED BEDS WITHIN THE 24 MONTHS PRECEDING THE APPLICATION DATE.
- (C) THE APPLICANT FACILITY SHALL PROPOSE, NO MORE THAN TWO BEDS PER RESIDENT ROOM AND SHALL ELIMINATE ALL THREE AND/OR FOUR BED WARDS WITHIN THE EXISTING FACILITY, IF APPLICABLE, AS PART OF THE PROPOSED PROJECT.
- (D) THE APPLICANT FACILITY SHALL CERTIFY THE NEW BEDS FOR BOTH MEDICARE AND MEDICAID.
- (E) THE APPLICANT FACILITY, SHALL NOT RELOCATE ANY BEDS FROM THE FACILITY OR REPLACE A PORTION OF BEDS TO A NEW SITE PURSUANT TO SECTION 7(3)(d), FOLLOWING CON APPROVAL AND FOR AT LEAST 24 MONTHS FROM THE DATE OF THE LICENSURE OF THE NEW BEDS AT THE FACILITY.
- (2) An applicant proposing to increase the number of nursing home beds in a planning area by beginning operation of a new nursing home/HLTCU or increasing the number of beds to an existing licensed nursing home/HLTCU pursuant to the new design model shall demonstrate the following:
- (a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing	All Michigan nursing homes/HLTCUs under
homes/HLTCUs	common ownership or control
Applicant with 10 or more Michigan nursing	All Michigan nursing homes/HLTCUs under
homes/HLTCUs and out of state nursing	common ownership or control
homes/HLTCUs	
Applicant with fewer than 10 Michigan nursing	All Michigan and out of state nursing
homes/HLTCUs and out of state nursing	homes/HLTCUs under common ownership or
homes/HLTCUs	control

- (i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.
  - (v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid

Deleted: The planning area in which the beds will be located shall have a population density of less than 28 individuals per square mile based on the 2010 U.S. Census figures as set forth in Appendix E.¶

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- (vi) Delinquent debt obligation to the State of Michigan including, but not limited to, Quality Assurance Assessment Program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or Civil Monetary Penalties (CMP).
- (b) The proposed project results in no more than 100 beds per new design model and meets the following design standards:
- (i) For inpatient facilities that are not limited to group resident housing of 10 beds or less, the construction standards shall be those applicable to nursing homes in the document entitled Minimum Design Standards for Health Care Facilities in Michigan and incorporated by reference in Section 20145(6) of the Public Health Code, being Section 333.20145(6) of the Michigan Compiled Laws or any future versions.
- (ii) For small resident housing units of 10 beds or less that are supported by a central support inpatient facility, the construction standards shall be those applicable to hospice residences providing an inpatient level of care, except that:
  - (A) at least 100% of all resident sleeping rooms shall meet barrier free requirements;
  - (B) electronic nurse call systems shall be required in all facilities;
  - (C) handrails shall be required on both sides of patient corridors; and
  - (D) ceiling heights shall be a minimum of 7 feet 10 inches.
- (iii) The proposed project shall comply with applicable life safety code requirements and shall be fully sprinkled and air conditioned.
- (iv) The Department may waive construction requirements for new design model projects if uthorized by law.
- (c) The proposed project shall include at least 80% single occupancy resident rooms with an adjoining toilet room containing a sink, water closet, and bathing facility and serving no more than two residents in both the central support inpatient facility and any supported small resident housing units.
- (d) The proposed increase, if approved, will not result in the total number of existing nursing home beds in that planning area exceeding the needed nursing home bed supply, unless the following is met:
- (i) An approved project involves replacement of a portion of the beds of an existing facility at a geographic location within the replacement zone that is not physically connected to the current licensed site. If a portion of the beds are replaced at a location that is not the current licensed site, a separate license shall be issued to the facility at the new location.
- (e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

#### Section 7. Requirements for approval to replace beds

- Sec. 7. An applicant proposing to replace beds must meet the following as applicable.
- (1) An applicant proposing to replace beds within the replacement zone shall not be required to be in compliance with the needed nursing home bed supply if all of the following requirements are met:
- (a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing	All Michigan nursing homes/HLTCUs under
homes/HLTCUs	common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control

Applicant with fewer than 10 Michigan nursing	All Michigan and out of state nursing
homes/HLTCUS and out of state nursing	homes/HLTCUs under common ownership or
homes/HLTCUs	control

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- (i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.
- (v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.
- (vi) Delinquent debt obligation to the State of Michigan including, but not limited to, Quality Assurance Assessment Program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or Civil Monetary Penalties (CMP).
- (b) The proposed project is either to replace the licensed nursing home/HLTCU to a new proposed licensed site or replace a portion of the licensed beds at the existing licensed site.
  - (c) The proposed licensed site is within the replacement zone.
- (d) The applicant certifies that the requirements found in the Minimum Design Standards for Health Care Facilities of Michigan, referenced in Section 20145 (6) of the Public Health Code, Act 368 of 1978, as amended and are published by the Department, will be met when the architectural blueprints are submitted for review and approval by the Department.
- (e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.
- (2) An applicant proposing to replace a licensed nursing home/HLTCU outside the replacement zone shall demonstrate all of the following:
- (a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing	All Michigan nursing homes/HLTCUs under
homes/HLTCUs	common ownership or control
Applicant with 10 or more Michigan nursing	All Michigan nursing homes/HLTCUs under
homes/HLTCUs and out of state nursing	common ownership or control
homes/HLTCUs	·
Applicant with fewer than 10 Michigan nursing	All Michigan and out of state nursing
homes/HLTCUs and out of state nursing	homes/HLTCUs under common ownership or
homes/HLTCUs	control

- (i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (ii) A filling for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.
- (v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.
- (vi) Delinquent debt obligation to the State of Michigan including, but not limited to, Quality Assurance Assessment Program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or Civil Monetary Penalties (CMP).
- (b) The total number of existing nursing home beds in that planning area is equal to or less than the needed nursing home bed supply.
- (c) The number of beds to be replaced is equal to or less than the number of currently licensed beds at the nursing home/HLTCU at which the beds proposed for replacement are currently located.
- (d) The applicant certifies that the requirements found in the Minimum Design Standards for Health Care Facilities of Michigan, referenced in Section 20145 (6) of the Public Health Code, Act 368 of 1978, as amended and are published by the Department, will be met when the architectural blueprints are submitted for review and approval by the Department.
- (e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.
- (3) An applicant proposing to replace beds with a new design model shall not be required to be in compliance with the needed nursing home bed supply if all of the following requirements are met:
- (a) The proposed project results in no more than 100 beds per new design model and meets the following design standards:
- (i) For inpatient facilities that are not limited to group resident housing of 10 beds or less, the construction standards shall be those applicable to nursing homes in the document entitled Minimum Design Standards for Health Care Facilities in Michigan and incorporated by reference in Section 20145(6) of the Public Health Code, being Section 333.20145(6) of the Michigan Compiled Laws or any future versions.
- (ii) For small resident housing units of 10 beds or less that are supported by a central support inpatient facility, the construction standards shall be those applicable to hospice residences providing an inpatient level of care, except that:
  - (a) at least 100% of all resident sleeping rooms shall meet barrier free requirements;
  - (b) electronic nurse call systems shall be required in all facilities;
  - (c) handrails shall be required on both sides of patient corridors; and
  - (d) ceiling heights shall be a minimum of 7 feet 10 inches.

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- (iii) The proposed project shall comply with applicable life safety code requirements and shall be fully sprinkled and air conditioned.
- (iv) The Department may waive construction requirements for new design model projects if authorized by law.
- (b) The proposed project shall include at least 80% single occupancy resident rooms with an adjoining toilet room containing a sink, water closet, and bathing facility and serving no more than two residents in both the central support inpatient facility and any supported small resident housing units. If the proposed project is for replacement/renovation of an existing facility and utilizes only a portion of its currently licensed beds, the remaining rooms at the existing facility shall not exceed double occupancy.
- (c) The proposed project shall be within the replacement zone unless the applicant demonstrates all of the following:
  - (i) the proposed licensed site for the replacement beds is in the same planning area,
- (ii) the applicant shall provide a signed affidavit or resolution from its governing body or authorized agent stating that the proposed licensed site will continue to provide service to the same market, and
- (iii) the current patients of the facility/beds being replaced shall be admitted to the replacement beds when the replacement beds are licensed, to the extent that those patients desire to transfer to the replacement facility/beds.
- (d) An approved project may involve replacement of a portion of the beds of an existing facility at a geographic location within the replacement zone that is not physically connected to the current licensed site. If a portion of the beds are replaced at a location that is not the current licensed site, a separate license shall be issued to the facility at the new location. IF BEDS HAVE BEEN ADDED PURSUANT TO SECTION 6(1)(d)(ii), THEN THE APPLICANT FACILITY SHALL NOT RELOCATE ANY BEDS FROM THE FACILITY OR REPLACE A PORTION OF BEDS TO A NEW SITE FOLLOWING CON APPROVAL AND FOR AT LEAST 24 MONTHS FROM THE DATE OF THE LICENSURE OF THE NEW BEDS AT THE FACILITY.
- (e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

#### Section 8. Requirements for approval to relocate existing nursing home/HLTCU beds

- Sec. 8. (1) An applicant proposing to relocate existing nursing home/HLTCU beds shall not be required to be in compliance with the needed nursing home bed supply if all of the following requirements are met:
- (a) There shall not be any ownership relationship requirements between the nursing home/HLTCU from which the beds are being relocated and the nursing home/HLTCU receiving the beds.
  - (b) The relocated beds shall be placed in the same planning area.
- (c) The relocated beds shall be licensed to the receiving nursing home/HLTCU and will be counted in the inventory for the applicable planning area.
- (d) At the time of transfer to the receiving facility, patients in beds to be relocated must be given the choice of remaining in another bed in the nursing home/HLTCU from which the beds are being transferred or to the receiving nursing home/HLTCU. Patients shall not be involuntary discharged to create a vacant bed.
- (e) Relocation of beds shall not increase the rooms with three (3) or more bed wards in the receiving facility.
- (f) IF BEDS HAVE BEEN ADDED PURSUANT TO SECTION 6(1)(d)(ii), THEN THE APPLICANT FACILITY SHALL NOT RELOCATE ANY BEDS FROM THE FACILITY OR REPLACE A PORTION OF BEDS TO A NEW SITE FOLLOWING CON APPROVAL AND FOR AT LEAST 24 MONTHS FROM THE DATE OF THE LICENSURE OF THE NEW BEDS AT THE FACILITY.

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(2) An applicant proposing to add new nursing home/HLTCU beds, as the receiving existing nursing home/HLTCU under subsection (1), shall not be required to be in compliance with the needed nursing home bed supply if all of the following requirements are met:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing	All Michigan nursing homes/HLTCUs under
homes/HLTCUs	common ownership or control
Applicant with 10 or more Michigan nursing	All Michigan nursing homes/HLTCUs under
homes/HLTCUs and out of state nursing	common ownership or control
homes/HLTCUs	
Applicant with fewer than 10 Michigan nursing	All Michigan and out of state nursing
homes/HLTCUs and out of state nursing	homes/HLTCUs under common ownership or
homes/HLTCUs	control

- (i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.
- (v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.
- (vi) Delinquent debt obligation to the State of Michigan including, but not limited to, Quality Assurance Assessment Program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or Civil Monetary Penalties (CMP).
- (b) The approval of the proposed new nursing home/HLTCU beds shall not result in an increase in the number of nursing home beds in the planning area.
- (c) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

#### Section 9. Requirements for approval to acquire an existing nursing home/HLTCU or renew the lease of an existing nursing home/HLTCU

Sec. 9. An applicant proposing to acquire an existing nursing home/HLTCU or renew the lease of an existing nursing home/HLTCU must meet the following as applicable:

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(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing	All Michigan nursing homes/HLTCUs under
homes/HLTCUs	common ownership or control
Applicant with 10 or more Michigan nursing	All Michigan nursing homes/HLTCUs under
homes/HLTCUs and out of state nursing	common ownership or control
homes/HLTCUs	·
Applicant with fewer than 10 Michigan nursing	All Michigan and out of state nursing
homes/HLTCUs and out of state nursing	homes/HLTCUs under common ownership or
homes/HLTCUs	control

- (i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (iii) termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.
- (v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.
- (vi) Delinquent debt obligation to the state of Michigan including, but not limited to, quality assurance assessment program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or civil monetary penalties (CMP).
  - (b) The acquisition will not result in a change in bed capacity.
  - (c) The licensed site does not change as a result of the acquisition.
  - (d) The project is limited solely to the acquisition of a nursing home/HLTCU with a valid license.
- (e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with the Department, and
- (f) The applicant shall participate in a quality improvement program, approved by the Department, for five years and provide an annual report to the Michigan State Long-Term-Care Ombudsman, Bureau of Health Care Services within LARA, and shall post the annual report in the facility if the facility being acquired has met any of conditions in subsections (a)(i), (ii), (iii), (iv), (v), or (vi).
- (g) IF THE APPLICANT IS A NEW ENTITY WITH NO PRIOR NH-HLTCU HISTORY, THE APPLICANT SHALL SUBMIT PROOF THAT:

- (i) THE NURSING HOME/HLTCU TO BE ACQUIRED IS NO LONGER LISTED AS A SPECIAL FOCUS NURSING HOME BY THE CENTER FOR MEDICARE AND MEDICAID SERVICES, OR THE APPLICANT SHALL PARTICIPATE IN A QUALITY IMPROVEMENT PROGRAM, APPROVED BY THE DEPARTMENT, FOR FIVE YEARS AND PROVIDE AN ANNUAL REPORT TO THE MICHIGAN STATE LONG-TERM-CARE OMBUDSMAN, BUREAU OF HEALTH CARE SERVICES WITHIN LARA, AND SHALL POST THE ANNUAL REPORT IN THE FACILITY; AND
- (ii) ALL DELINQUENT DEBT OBLIGATIONS TO THE STATE OF MICHIGAN INCLUDING, BUT NOT LIMITED TO, QAAP, PASARR OR CMPs HAVE BEEN PAID.
- (2) An applicant proposing to acquire an existing nursing home/HLTCU approved pursuant to the new design model shall demonstrate the following:
- (a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing	All Michigan nursing homes/HLTCUs under
homes/HLTCUs	common ownership or control
Applicant with 10 or more Michigan nursing	All Michigan nursing homes/HLTCUs under
homes/HLTCUs and out of state nursing	common ownership or control
homes/HLTCUs	
Applicant with fewer than 10 Michigan nursing	All Michigan and out of state nursing
homes/HLTCUs and out of state nursing	homes/HLTCUs under common ownership or
homes/HLTCUs	control

- (i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- (iv) A number of citations at level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.
- (v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.
- (vi) Delinquent debt obligation to the State of Michigan including, but not limited to, Quality Assurance Assessment Program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or Civil Monetary Penalties (CMP).
- (b) An applicant will continue to operate the existing nursing home/HLTCU pursuant to the new design model requirements.
- (c) The applicant shall participate in a quality improvement program, approved by the Department, for five years and provide an annual report to the Michigan State Long-Term-Care Ombudsman, Bureau

- of Health of Health Care Services within LARA, and shall post the annual report in the facility being acquired has met any of conditions in subsections (a)(i), (ii), (iii), (iv), (v), or (vi).
- (d) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.
- (e) IF THE APPLICANT IS A NEW ENTITY WITH NO PRIOR NH-HLTCU HISTORY, THE APPLICANT SHALL SUBMIT PROOF THAT:
- (i) THE NURSING HOME/HLTCU TO BE ACQUIRED IS NO LONGER LISTED AS A SPECIAL FOCUS NURSING HOME BY THE CENTER FOR MEDICARE AND MEDICAID SERVICES, OR THE APPLICANT SHALL PARTICIPATE IN A QUALITY IMPROVEMENT PROGRAM, APPROVED BY THE DEPARTMENT, FOR FIVE YEARS AND PROVIDE AN ANNUAL REPORT TO THE MICHIGAN STATE LONG-TERM-CARE OMBUDSMAN, BUREAU OF HEALTH CARE SERVICES WITHIN LARA, AND SHALL POST THE ANNUAL REPORT IN THE FACILITY; AND
- (ii) ALL DELINQUENT DEBT OBLIGATIONS TO THE STATE OF MICHIGAN INCLUDING, BUT NOT LIMITED TO, QAAP, PASARR OR CMPs HAVE BEEN PAID.
- (3) An applicant proposing to renew the lease for an existing nursing home/HLTCU shall not be required to be in compliance with the needed nursing home bed supply for the planning area in which the nursing home/HLTCU is located, if all of the following requirements are met:
  - (a) The lease renewal will not result in a change in bed capacity.
  - (b) The licensed site does not change as a result of the lease renewal.
- (c) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

#### Section 10. Review standards for comparative review

- Sec. 10. (1) Any application subject to comparative review, under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and reviewed comparatively with other applications in accordance with the CON rules.
- (2) The degree to which each application in a comparative group meets the criterion set forth in Section 22230 of the Code, being Section 333.22230 of the Michigan Compiled Laws, shall be determined based on the sum of points awarded under subsections (a) and (b).
  - (a) A qualifying project will be awarded points as follows:
- (i) For an existing nursing home/HLTCU, the current percentage of patient days of care reimbursed by Medicaid for the most recent 12 months of operation.
- (ii) For a new nursing home/HLTCU, the proposed percentage of patient days of care to be reimbursed by Medicaid in the second 12 months of operation following project completion.

Percentage of Medicaid Patient Days	Points Awarded	
(calculated using total patient days for all existing and proposed beds at the facility)	Existing	Proposed
50 – 69%	4	3
70 – 100%	8	7

- (b) A qualifying project will be awarded 10 points if all beds in the proposed project will be dually certified for both Medicare and Medicaid services by the second 12 months of operation.
- (3) A qualifying project will have 15 points deducted if the applicant has any of the following at the time the application is submitted:

- (a) has been a special focus nursing home/HLTCU within the last three (3) years;
- (b) has had more than eight (8) substandard quality of care citations; immediate harm citations, and/or immediate jeopardy citations in the three (3) most recent standard survey cycles (includes intervening abbreviated surveys, standard surveys, and revisits);
- (c) has had an involuntary termination or voluntary termination at the threat of a medical assistance provider enrollment and trading partner agreement within the last three (3) years;
- (d) has had a state enforcement action resulting in a reduction in license capacity or a ban on admissions within the last three (3) years; or
- (e) has any delinquent debt obligation to the state of Michigan including, but not limited to, quality assurance assessment program (QAAP), civil monetary penalties (CMP), Medicaid level of care determination (LOCD), or preadmission screening and annual resident review (PASARR).
- (4) A qualifying project will be awarded three (3) points if the applicant provides documentation that it participates or if it proposes to participate in a culture change model, which contains person centered care, ongoing staff training, and measurements of outcomes. An additional five (5) points will be awarded if the culture change model, either currently used or proposed, is a model approved by the Department.
- (5) A qualifying project will be awarded points based on the proposed percentage of the "Applicant's cash" to be applied toward funding the total proposed project cost as follows:

Percentage "Applicant's Cash"	Points Awarded
Over 20%	5
10 – 20%	3
5 – 9%	2

- (6) A qualifying project will be awarded four (4) points if the entire existing and proposed nursing home/HLTCU is fully equipped with air conditioning. Fully equipped with air conditioning means meeting the design temperatures in table 6b of the minimum design standards for health care facilities in Michigan and capable of maintaining a temperature of 71-81 degrees for the resident unit corridors.
- (7) A qualifying project will be awarded six (6) or four (4) points based on only one of the following:
   (a) Six (6) points if the proposed project has 100% rooms with dedicated toilet room containing a sink, water closet, and bathing facility or
- (b) Four (4) points if the proposed project has 80% private rooms with dedicated toilet room containing a sink, water closet and bathing facility.
- (8) A qualifying project will be awarded 10 points if it results in a nursing home/HLTCU with 150 or fewer beds in total.
- (9) A qualifying project will be awarded five (5) points if the proposed beds will be housed in new construction.
- (10) A qualifying project will be awarded 10 points if the entire existing nursing home/HLTCU and its proposed project will have no more than double occupancy rooms at completion of the project.
- (11) A qualifying project will be awarded two (2) points if the existing or proposed nursing home/HLTCU is on or readily accessible to an existing or proposed public transportation route.
  - (12) A qualifying project will be awarded points for technological innovation as follows:

INNOVATIONS	Points Awarded
The proposed project will have wireless nurse call/paging system including wireless devices carried by direct care staff	1
Wireless internet with resident access to related equipment/device in entire facility	1
An integrated electronic medical records system with point- of-service access capability (including wireless devices) for all disciplines including pharmacy, physician, nursing, and therapy services at the entire existing and proposed nursing home/HLTCU	4
The proposed project will have a backup generator supporting all functions with an on-site or piped-in fuel supply and be capable of providing at least 48 hours of service at full load	4

(13) A qualifying project will be awarded three (3) points if the proposed project includes bariatric
rooms as follows: project using 0 - 49 beds will result in at least one (1) bariatric room or project using 50
or more beds will result in at least two (2) bariatric rooms. Bariatric room means the creation of patient
room(s) included as part of the CON project, and identified on the architectural schematics, that are
designed to accommodate the needs of bariatric patients weighing over 350 pounds. The bariatric patient
rooms shall have a larger ENTRANCE WIDTH FOR THE ROOM and bathroom to accommodate over-
sized equipment, and shall include a minimum of a bariatric bed, bariatric toilet, bariatric wheelchair, and
a device to assist resident movement (such as a portable or build in lift). If an in-room shower is not
included in the bariatric patient room, the main/central shower room that is located on the same floor as
the bariatric patient room(s) shall include at least one (1) shower stall that has an opening width and
depth that is larger than minimum MI code requirements.

- (14) 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.
- (15) 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, being Section 333.22225(1) of the Michigan Compiled Laws, and which have the highest number of points when the results of subsections (2) through (12) 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, as defined in Section 22225(1), in the order in which the applications were received by the Department, based on the date and time stamp on the application when the application is filed.

#### Section 11. Project delivery requirements and terms of approval

Sec. 11. An applicant shall agree that, if approved, the nursing home/HLTCU services shall be delivered in compliance with the following terms of approval:

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- (1) Compliance with these standards, including the requirements of Section 10. If an applicant is awarded beds pursuant to Section 10 and representations made in that section, the Department shall monitor compliance with those statements and representations and shall determine actions for non-
  - (2) Compliance with the following applicable quality assurance standards:
- (a) Compliance with Section 22230 of the Code shall be based on the nursing home's/HLTCU's actual Medicaid participation within the time periods specified in these standards. Compliance with Section 10(2)(a) of these standards shall be determined by comparing the nursing home's/HLTCU's actual patient days reimbursed by Medicaid, as a percentage of the total patient days, with the applicable schedule set forth in Section 10(2)(a) for which the applicant had been awarded points in the comparative review process. If any of the following occurs, an applicant shall be required to be in compliance with the range in the schedule immediately below the range for which points had been awarded in Section 10(2)(a), instead of the range of points for which points had been awarded in the comparative review in order to be found in compliance with Section 22230 of the Code: (i) the average percentage of Medicaid recipients in all nursing homes/HLTCUs in the planning area decreased by at least 10 percent between the second 12 months of operation after project completion and the most recent 12-month period for which data are available, (ii) the actual rate of increase in the Medicaid program per diem reimbursement to the applicant nursing home/HLTCU is less than the annual inflation index for nursing homes/HLTCUs as defined in any current approved Michigan State Plan submitted under Title XIX of the Social Security Act which contains an annual inflation index, or (iii) the actual percentage of the nursing home's/HLTCU's patient days reimbursed by Medicaid (calculated using total patient days for all existing and proposed nursing home beds at the facility) exceeds the statewide average plus 10 percent of the patient days reimbursed by Medicaid for the most recent year for which data are available from the Michigan Department of Health AND HUMAN SERVICES [subsection (iii) is applicable only to Section 10(2)(a)]. Ir evaluating subsection (ii), the Department shall rely on both the annual inflation index and the actual rate increases in per diem reimbursement to the applicant nursing home/HLTCU and/or all nursing homes/HLTCUs in the HSA.
- (b) For projects involving the acquisition of a nursing home/HLTCU, the applicant shall agree to maintain the nursing home's/HLTCU's level of Medicaid participation (patient days and new admissions) for the time periods specified in these standards, within the ranges set forth in Section 10(2)(a) for which the seller or other previous owner/lessee had been awarded points in a comparative review.
- (c) For projects involving replacement of an existing nursing home/HLTCU, the current patients of the facility/beds being replaced shall be admitted to the replacement beds when the replacement beds are licensed, to the extent that those patients desire to transfer to the replacement facility/beds.
- (d) The applicant will assure compliance with Section 20201 of the Code, being Section 333.20201 of the Michigan Compiled Laws.
  - (3) Compliance with the following access to care requirements:
- (a) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:
  - (i) not deny services to any individual based on payor source.
- (ii) maintain information by source of payment to indicate the volume of care from each payor and non-payor source provided annually.
  - (iii) provide services to any individual based on clinical indications of need for the services.
  - (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; 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

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required data on an individual 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.

- (b) The applicant shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.
- (5) An applicant shall agree that, if approved, and material discrepancies are later determined within the reporting of the ownership and citation history of the applicant facility and all nursing homes under common ownership and control that would have resulted in a denial of the application, shall surrender the CON. This does not preclude an applicant from reapplying with corrected information at a later date.
- (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 12. Department inventory of beds

Sec. 12. The Department shall maintain a listing of the Department Inventory of Beds for each planning area.

#### Section 13. Wayne County planning areas

Sec. 13. (1) For purposes of these standards the cities and/or townships in Wayne County are assigned to the planning areas as follows:

#### Planning Area 84/Northwest Wayne

Canton Township, Dearborn, Dearborn Heights, Garden City, Inkster, Livonia, Northville (part), Northville Township, Plymouth, Plymouth Township, Redford Township, Wayne, Westland

#### Planning area 85/Southwest Wayne

Allen Park, Belleville, Brownstown Township, Ecorse, Flat Rock, Gibraltar, Grosse Ile Township, Huron Township, Lincoln Park, Melvindale, River Rouge, Riverview, Rockwood, Romulus, Southgate, Sumpter Township, Taylor, Trenton, Van Buren Township, Woodhaven, Wyandotte

### Planning area 86/Detroit

Detroit, Grosse Pointe, Grosse Pointe Township, Grosse Pointe Farms, Grosse Pointe Park, Grosse Pointe Woods, Hamtramck, Harper Woods, Highland Park

#### Section 14. Effect on prior CON review standards, comparative reviews

- Sec. 14. (1) These CON review standards supersede and replace the CON Standards for Nursing Home and Hospital Long-Term-Care Unit (HLTCU) Beds approved by the CON Commission on December 11, 2014 and effective on March 20, 2015.
- (2) Projects reviewed under these standards involving a change in bed capacity shall be subject to comparative review except as follows:
- (a) replacement of an existing nursing home/HLTCU being replaced in THE REPLACEMENT ZONE;

CON Review Standards for Nursing Home and HLTCU Beds For Proposed Action 3-16-17 Commission Meeting HIGHLIGHTED Text – Proposed edits CON-217 | | Page 18 of 34 Deleted: 15
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(b) replacement of an existing nursing home/HLTCU PURSUANT TO SECTION 7(3) AND WITHIN THE SAME PLANNING AREA AS THE EXISTING LICENSED SITE;

- (c) relocation of existing nursing home/HLTCU beds; or
- (d) an increase in beds pursuant to Section 6(1)(d)(ii)

(3) Projects reviewed under these standards that relate solely to the acquisition of an existing nursing home/HLTCU or the renewal of a lease shall not be subject to comparative review.

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907	Counties assigned to ea	ach of the HSAs are as follo	OWS:		
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909	HSA	COUNTIES			
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911	1	Livingston	Monroe	St. Clair	
912		Macomb	Oakland	Washtenaw	
913		Wayne			
914	_				
915	2	Clinton	Hillsdale	Jackson	
916		Eaton	Ingham	Lenawee	
917	_	_	- "		
918	3	Barry	Calhoun	St. Joseph	
919		Berrien	Cass	Van Buren	
920		Branch	Kalamazoo		
921					
922	4	Allegan	Mason	Newaygo	
923		Ionia	Mecosta	Oceana	
924		Kent	Montcalm	Osceola	
925		Lake	Muskegon	Ottawa	
926		_			
927	5	Genesee	Lapeer	Shiawassee	
928				_	
929	6	Arenac	Huron	Roscommon	
930		Bay	losco	Saginaw	
931		Clare	Isabella	Sanilac	
932		Gladwin	Midland	Tuscola	
933		Gratiot	Ogemaw		
934	_				
935	7	Alcona	Crawford	Missaukee	
936		Alpena	Emmet	Montmorency	
937		Antrim	Gd Traverse	Oscoda	
938		Benzie	Kalkaska	Otsego	
939		Charlevoix	Leelanau	Presque Isle	
940		Cheboygan	Manistee	Wexford	
941	0	A1	O a malaia	Mandalana	
942	8	Alger	Gogebic	Mackinac	
943		Baraga	Houghton	Marquette	
944		Chippewa	Iron	Menominee	
945		Delta	Keweenaw	Ontonagon	
946		Dickinson	Luce	Schoolcraft	
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CON Review Standards for Nursing Home and HLTCU Beds For Proposed Action 3-16-17 Commission Meeting HIGHLIGHTED Text – Proposed edits

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APPENDIX A

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FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT BEDS¶
The use rate per 1000 population for each age cohort, for purposes of these standards, effective August MARCH 16, 20132016, and until otherwise changed by the Commission, is as follows.¶
(ii) . Age 0 - 64: . 200 195 days of care ¶
(iii) . Age 65 - 74: . 2,6382,380 days of care ¶
(iii) . Age 75 - 84: . 9,3798,091 days of care ¶
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    CON REVIEW STANDARDS TFOR NURSING HOME AND HOSPITAL LONG-TERM-
 CARE UNIT BEDS¶

The ADC adjustment factor, for purposes of these standards, effective August 1, 2013, and until otherwise changed by the Commission, are as follows:¶
ADC¶
Adjustment¶
  Planning Area Factor
    Alcona 0.90¶
Alger 0.90¶
Allegan 0.95¶
   Alpena 0.95¶
Antrim 0.95¶
     Arenac 0.90¶
   ¶
Baraga 0.90¶
Barry 0.95¶
Bay 0.95¶
Benzie 0.95¶
Berrien 0.95¶
Branch 0.95¶
Delta . . . 0.95¶
Dickinson . . 0.95¶
 Eaton ... 0.95¶
Emmet ... 0.95¶

Genesee ... 0.95¶
Gladwin ... 0.95¶
Gogebic ... 0.95¶
Gd. Traverse ... 0.95¶
Genese ... 0.95¶
     Gratiot 0.95¶
Hillsdale 0.95¶
Houghton/Keweenaw 0.95¶
Huron 0.95¶

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APPENDIX C - continued¶

APPENDIX C - continued¶
 ADC¶
Adjustment¶
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  Ingham 0.95¶
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Iosco 0.95¶
                      0.90¶
    Iron . . . .
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CON Review Standards for Nursing Home and HLTCU Beds For Proposed Action 3-16-17 Commission Meeting HIGHLIGHTED Text — Proposed edits CON-217

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1129	Rural Michigan counties are as	follows:	
1130	rtara mongan ocamico are ac		
	Alaana	Carabia	Oneman
1131	Alcona	Gogebic	Ogemaw
1132	Alger	Huron	Ontonagon
1133	Antrim	losco	Osceola
1134	Arenac	Iron	Oscoda
1135	Baraga	Lake	Otsego
1136	Charlevoix	Luce	Presque Isle
1137	Cheboygan	Mackinac	Roscommon
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1138	Clare	Manistee	Sanilac
1139	Crawford	Montmorency	Schoolcraft
1140	Emmet	Newaygo	Tuscola
1141	Gladwin	Oceana	
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1143	Micropolitan statistical area Mic	higan counties are as follows:	
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	Alpena	Houghton	Mecosta
1146	•		
1147	Benzie	Ionia	Menominee
1148	Branch	Isabella	Missaukee
1149	Chippewa	Kalkaska	St. Joseph
1150	Delta	Keweenaw	Shiawassee
1151	Dickinson	Leelanau	Wexford
1152	Grand Traverse	Lenawee	
1153	Gratiot	Marquette	
1154			
1155	Metropolitan statistical area Mic	chigan counties are as follows:	
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1157	Barry	Jackson	Muskegon
1158	Bay	Kalamazoo	Oakland
1159	Berrien	Kent	Ottawa
	Calhoun	Lapeer	Saginaw
1160			
1161	Cass	Livingston	St. Clair
1162	Clinton	Macomb	Van Buren
1163	Eaton	Midland	Washtenaw
1164	Genesee	Monroe	Wayne
1165	Ingham	Montcalm	
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1167	Source:		
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1169	75 F.R., p. 37245 (June 28, 201	10)	
		10)	
1170	Statistical Policy Office	-1 Aff-i	
1171	Office of Information and Regul		
1172	United States Office of Manage	ment and Budget	
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CON Review Standards for Nursing Home and HLTCU Beds For Proposed Action 3-16-17 Commission Meeting HIGHLIGHTED Text – Proposed edits

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APPENDIX B

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# MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

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# CON REVIEW STANDARDS FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS --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 Nursing Home and Hospital Long-term Care Unit Beds and shall be used for determining the need for projects established to better meet the needs of special population groups within the long-term care and nursing home populations.
- (2) Except as provided in sections 2, 3, 4, 5, 6, 7, and 8 of this addendum, these standards supplement, and do not supersede, the requirements and terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds.
- (3) The definitions which apply to the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds shall apply to these standards.
  - (4) For purposes of this addendum, the following terms are defined:
  - (a) "BARIATRIC PATIENT" MEANS A PATIENT WEIGHTING OVER 350, POUNDS.
- (b) "BARIATRIC ROOM" MEANS THE CREATION OF PATIENT ROOM(S) INCLUDED AS PART OF THE CON PROJECT, AND IDENTIFIED ON THE ARCHITECTURAL SCHEMATICS, THAT ARE DESIGNED TO ACCOMMODATE THE NEEDS OF BARIATRIC PATIENTS WEIGHING OVER 350 POUNDS. THE BARIATRIC PATIENT ROOMS SHALL HAVE A LARGER ENTRANCE WIDTH FOR THE ROOM AND BATHROOM TO ACCOMMODATE OVER-SIZED EQUIPMENT, AND SHALL INCLUDE A MINIMUM OF A BARIATRIC BED, BARIATRIC TOILET, BARIATRIC WHEELCHAIR, AND A DEVICE TO ASSIST RESIDENT MOVEMENT (SUCH AS A PORTABLE OR BUILD IN LIFT). IF AN IN-ROOM SHOWER IS NOT INCLUDED IN THE BARIATRIC PATIENT ROOM, THE MAIN/CENTRAL SHOWER ROOM THAT IS LOCATED ON THE SAME FLOOR AS THE BARIATRIC PATIENT ROOM(S) SHALL INCLUDE AT LEAST ONE (1) SHOWER STALL THAT HAS AN OPENING WIDTH AND DEPTH THAT IS LARGER THAN MINIMUM MI CODE REQUIREMENTS.
- (c) "Behavioral patient" means an individual that exhibits a history of chronic behavior management problems such as aggressive behavior that puts self or others at risk for harm, or an altered state of consciousness, including paranoia, delusions, and acute confusion.
- (d) "Infection control program," means a program that will reduce the risk of the introduction of communicable diseases into a ventilator-dependent unit, provide an active and ongoing surveillance program to detect the presence of communicable diseases in a ventilator-dependent unit, and respond to the presence of communicable diseases within a ventilator-dependent unit so as to minimize the spread of a communicable disease.
- (e) "Licensed hospital" means either a hospital licensed under Part 215 of the Code; or a psychiatric hospital or unit licensed pursuant to Act 258 of the Public Acts of 1974, as amended, being sections 330.1001 to 330.2106 of the Michigan Compiled Laws.
- (f) "Private residence", means a setting other than a licensed hospital; or a nursing home including a nursing home or part of a nursing home approved pursuant to Section 6.
- (g) "Traumatic brain injury (TBI)/spinal cord injury (SCI) patient" means an individual with TBI or SCI that is acquired or due to a traumatic insult to the brain and its related parts that is not of a

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et seq.¶

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CON REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM CARE
UNIT BEDS¶
... Michigan nursing home planning areas with a population
density of less than 28 individuals per square mile based on 2010 U.S. Census figures.¶
              Population Density¶
Area Per Square Mile
¶
Ontonagon 5.11¶
Schoolcraft 6.95
Luce 7.16¶
Baraga 9.67¶
Iron 9.76¶
Alger 10.25¶
Mackinac 10.45¶
Gogebic 14.35¶
Oscoda 15.12¶
Alcona 15.76¶
Montmorency 17.36¶
Presque Isle 19.53¶
Chippewa 21.29¶
Menominee 22.86¶
Houghton/Keweer
                      24.17¶
Crawford 25.00¶
Missaukee 25.90¶
Source: Michigan Department of Management and Budget
The U.S. Bureau of the Census¶
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degenerative or congenital nature. These impairments may be either temporary or permanent and cause partial or total functional disability or psychosocial adjustment.

(h) "Ventilator-dependent patient," means an individual who requires mechanical ventilatory

Section 2. Requirements for approval -- applicants proposing to increase nursing home beds --

Sec. 2. A project to increase nursing home beds in a planning area which, if approved, would otherwise cause the total number of nursing home beds in that planning area to exceed the needed nursing home bed supply or cause an increase in an existing excess as determined under the applicable CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds, may nevertheless be approved pursuant to this addendum.

# Section 3. Statewide pool for the needs of special population groups within the long-term care and nursing home populations

- Sec. 3. (1) A statewide pool of additional nursing home beds of 1,958 beds needed in the state is established to better meet the needs of special population groups within the long-term care and nursing home populations. Beds in the pool shall be allocated as follows:
- (a) These categories shall be allocated 1,039 beds and distributed as follows and shall be reduced/redistributed in accordance with subsection (c):
  - (i) TBI/SCI beds will be allocated 400 beds.
  - (ii) Behavioral beds will be allocated 400 beds.
  - (iii) BARIATRIC beds will be allocated 60 beds.
  - (iv) Ventilator-dependent beds will be allocated 179 beds.

(b)The following historical categories have been allocated 919 beds. Additional beds shall not be allocated to these categories. If the beds within any of these categories are delicensed, the beds shall be eliminated and not be returned to the statewide pool for special population groups.

- (i) Alzheimer's disease has 384 beds.
- (ii) Health care needs for skilled nursing care has 173 beds.
- (iii) Religious has 292 beds.

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assistance.

special use exceptions

(iv) Hospice beds has 70 beds.

(c) THE COMMISSION MAY ADJUST/REDISTRIBUTE THE NUMBER OF BEDS AVAILABLE IN THE STATEWIDE POOL FOR THE NEEDS OF SPECIAL POPULATION GROUPS IN SUBSECTION (1)(a) CONCURRENT WITH THE BIENNIAL RECALCUATION OF THE STATEWIDE NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BED NEED. MODIFYING THE NUMBER OF BEDS AVAILABLE IN THE STATEWIDE POOL FOR THE NEEDS OF SPECIAL POPULATION GROUPS IN SUBSECTION (1)(a) 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.

- (d) By setting aside these beds from the total statewide pool, the Commission's action applies only to applicants seeking approval of nursing home beds pursuant to sections 4, 5, 6, and 7. It does not preclude the care of these patients in units of hospitals, hospital long-term care units, nursing homes, or other health care settings in compliance with applicable statutory or certification requirements.
- (2) Increases in nursing home 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.

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- . (i) The number of beds in a special population group shall be reduced to the total number of beds for which a valid CON has been issued for that special population group.
- . (ii) The number of beds reduced from a special population group pursuant to this subsection shall revert to the total statewide pool established for categories in subsection (1)(a). ¶
- . (iii) . The Department shall notify the Commission of the date when action to reduce the number of beds set aside for a special population group has become effective and shall identify the number of beds that reverted to the total statewide pool established for categories in subsection (1)(a). ¶
  . (iv) . For purposes of this subsection, "application period"
- means the period of time from one designated application date to the next subsequent designated application date. ¶
  \_(v) For purposes of this subsection, "CON activity" means one or more of the following: ¶
- . (A) . CON applications for beds for a special population group have been submitted to the Department for which either a proposed or final decision has not yet been issued by the Department.
- (B) Administrative hearings or appeals to court of decisions issued on CON applications for beds for a special population group are pending resolution.
- (C). An approved CON for beds for each special population group has expired for lack of appropriate action by an applicant to implement an approved CON.

CON Review Standards for Nursing Home and HLTCU Beds For Proposed Action 3-16-17 Commission Meeting HIGHLIGHTED Text – Proposed edits CON-217

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 Section 4. Requirements for approval for beds from the statewide pool for special population groups allocated to TBI/SCI 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 TBI/SCI patients as compared to serving these needs in general nursing home unit(s).
- (1) An applicant proposing to begin operation of a new nursing home/HLTCU or add beds to an existing nursing home/HLTCU 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 TBI/SCI patients. At the time an application is submitted, the applicant shall demonstrate that it operates:
- (i) A continuum of outpatient treatment, rehabilitative care, and support services for TBI/SCI patients; and
- (ii) A transitional living program or contracts with an organization that operates a transitional living program and rehabilitative care for TBI/SCI patients.
- (b) The applicant shall submit evidence of accreditation of its existing outpatient and/or residential programs by the Commission on Accreditation of Rehabilitation Facilities (CARF) or another nationally-recognized accreditation organization for rehabilitative care and services.
- (c) Within 24-months of accepting its first patient, the applicant shall obtain CARF or another nationally-recognized accreditation organization for the nursing home beds proposed under this subsection.
- (d) A floor plan for the proposed physical plant space to house the nursing home beds allocated under this subsection that provides for:
  - (i) Individual units consisting of 20 beds or less per unit, not to be more than 40 beds per facility.
- (ii) Day/dining area within, or immediately adjacent to, the unit(s), which is solely for the use of TBI/SCI patients.
- (iii) Direct access to a secure outdoor or indoor area at the facility appropriate for supervised activity.
- (e) The applicant proposes programs to promote a culture within the facility that is appropriate for TBI/SCI patients of various ages.
- (2) Beds approved under this subsection shall not be converted to OR UTILIZED AS general nursing home use without a CON for nursing home and hospital long-term care unit beds under the CON review standards for nursing home and hospital long-term care unit beds and shall not be offered to individuals other than TBI/SCI patients.

# Section 5. Requirements for approval for beds from the statewide pool for special population groups allocated to behavioral 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 behavioral patients as compared to serving these needs in general nursing home unit(s).
- (1) An applicant proposing to begin operation of a new nursing home/HLTCU or add beds to an existing nursing home/HLTCU under this section shall demonstrate with credible documentation to the satisfaction of the Department each of the following:
  - (a) Individual units shall consist of 20 beds or less per unit.
  - (b) The facility shall not be awarded more than 40 beds.
- (c) The proposed unit shall have direct access to a secure outdoor or indoor area for supervised activity.
- (d) The unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the behavioral patients.

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- (e) The physical environment of the unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.
  - (f) Staff will be specially trained in treatment of behavioral patients.
- (2) Beds approved under this subsection shall not be converted to OR UTILIZED AS general nursing home use without a CON for nursing home and hospital long-term care unit beds under the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds.
- (3) 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 BARIATRIC 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 BARIATRIC PATIENTS AS COMPARED TO SERVING THESE NEEDS IN GENERAL NURSING HOME UNIT(S).

- (1) An applicant proposing to begin operation of a new nursing home/HLTCU or add beds to an existing nursing home/HLTCU under this section shall demonstrate, with credible documentation to the satisfaction of the Department, each of the following:
  - (a) THE FACILITY SHALL NOT BE AWARDED MORE THAN 10 BEDS
- THE FACILITY MAY PLACE BEDS THROUGHOUT THE FACILITY FOR A FLEXIBLE AND SEAMLESS INCLUSIVE RESIDENT DESIGN
- (c) THE PROPOSED BEDS SHALL HAVE ADEQUATE ACCESS TO AN OUTDOOR OR
- INDOOR AREA FOR ACTIVITIES WITH APPROPRIATE EQUIPMENT,
- THE PHYSICAL ENVIRONMENT OF ANY UNIT CONTAINING BARIATRIC BEDS SHALL BE **DESIGNED TO FACILITATE VISITORS**
- THE UNIT/BEDS SHALL HAVE AVAILABLE SPECIALTY EQUIPMENT TO ASSIST STAFF II PROVIDING CARE
- (f) THE BEDS SHALL BE LOCATED ON A GROUND FLOOR AND EMERGENCY EGRESS WILL NOT REQUIRE STAIRWAYS OR ELEVATORS TO EXIT,
- (g) THE BEDS SHALL BE ESTABLISHED IN EITHER SINGLE OR DOUBLE OCCUPANCY ROOMS, THERE SHALL BE NO ROOMS WITH MORE THAN TWO BEDS
- BEDS APPROVED UNDER THIS SUBSECTION SHALL NOT BE CONVERTED TO OR UTILIZED FOR GENERAL NURSING HOME USE WITHOUT A CON FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS.
- (3) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

#### Section 7. Requirements for approval for beds from the statewide pool for special population groups allocated to ventilator-dependent patients

- Sec. 7. The CON Commission determines there is a need for beds for ventilator-dependent patients within the long-term care and nursing home populations
- (1) An applicant proposing to begin operation of a new nursing home/HLTCU or add beds to an existing nursing home/HLTCU under this section shall demonstrate, with credible documentation to the satisfaction of the Department, each of the following:
- (a) An applicant proposes a program for caring for ventilator-dependent patients in licensed nursing home beds.

CON Review Standards for Nursing Home and HLTCU Beds For Proposed Action 3-16-17 Commission Meeting HIGHLIGHTED Text - Proposed edits

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- (b) An application proposes no more than 40 beds that will be licensed as nursing home beds.
- (c) The proposed unit will serve only ventilator-dependent patients.
- (2) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.
- (3) BEDS APPROVED UNDER THIS SUBSECTION SHALL NOT BE CONVERTED TO OR UTILIZED FOR GENERAL NURSING HOME USE WITHOUT A CON FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS.

### Section 8. Acquisition of nursing home/HLTCU beds approved pursuant to this addendum

Sec. 8. (1) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to religious shall meet the following:

- (a) The applicant is a part of, closely affiliated with, controlled, sanctioned or supported by a recognized religious organization, denomination or federation as evidenced by documentation of its federal tax exempt status as a religious corporation, fund, or foundation under section 501(c)(3) of the United States Internal Revenue Code.
- (b) The applicant's patient population includes a majority of members of the religious organization or denomination represented by the sponsoring organization.
- (c) The applicant's existing services and/or operations are tailored to meet certain special needs of a specific religion, denomination or order, including unique dietary requirements, or other unique religious needs regarding ceremony, ritual, and organization which cannot be satisfactorily met in a secular setting.
- (d) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.
- (2) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to TBI/SCI shall meet the following:
- (a) The beds will be operated as part of a specialized program exclusively for TBI/SCI patients. At the time an application is submitted, the applicant shall demonstrate that it operates:
- (i) a continuum of outpatient treatment, rehabilitative care, and support services for TBI/SCI patients: and
- (ii) a transitional living program or contracts with an organization that operates a transitional living program and rehabilitative care for TBI/SCI patients.
- (b) The applicant shall submit evidence of accreditation of its existing outpatient and/or residential programs by the Commission on Accreditation of Rehabilitation Facilities (CARF) or another nationallyrecognized accreditation organization for rehabilitative care and services.
- (c) Within 24-months of accepting its first patient, the applicant shall obtain CARF or another nationally-recognized accreditation organization for the nursing home beds proposed under this subsection.
- (d) A floor plan for the proposed physical plant space to house the nursing home beds allocated under this subsection that provides for:
  - (i) Individual units consisting of 20 beds or less per unit, not to be more than 40 beds per facility.
- (ii) Day/dining area within, or immediately adjacent to, the unit(s), which is solely for the use of TBI/SCI patients.
- (iii) Direct access to a secure outdoor or indoor area at the facility appropriate for supervised activity.
- The applicant proposes programs to promote a culture within the facility that is appropriate for TBI/SCI patients of various ages.
- (3) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to Alzheimer's disease shall meet the following:

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- (a) The beds are part of a specialized program for Alzheimer's disease which will admit and treat only patients which require long-term nursing care and have been appropriately classified as a patient on the Global Deterioration Scale (GDS) for age-associated cognitive decline and Alzheimer's disease as a level 4 (when accompanied by continuous nursing needs), 5, or 6.
  - (b) The specialized program will participate in the state registry for Alzheimer's disease.
- (c) The specialized program shall be attached or geographically adjacent to a licensed nursing home and be no larger than 20 beds in size.
- (d) The proposed Alzheimer's unit shall have direct access to a secure outdoor or indoor area at the health facility, appropriate for unsupervised activity.
- (e) The Alzheimer's unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the Alzheimer's unit patients.
- (f) The physical environment of the Alzheimer's unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.
  - (g) Staff will be specially trained in Alzheimer's disease treatment.
- (h) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.
- (4) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to behavioral patients shall meet the following:
  - (a) Individual units shall consist of 20 beds or less per unit.
  - The facility shall not be awarded more than 40 beds.
- The proposed unit shall have direct access to a secure outdoor or indoor area for supervised (c) activity.
- (d) The unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the behavioral patients.
- (e) The physical environment of the unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.
  - (f) Staff will be specially trained in treatment of behavioral patients.
- (g) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.
- (5) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to hospice shall meet the following:
- (a) An applicant shall be a hospice certified by Medicare pursuant to the code of Federal Regulations, Title 42, Chapter IV, Subpart B (Medicare Programs), Part 418 and shall have been a Medicare certified hospice for at least 24 continuous months prior to the date an application is submitted to the Department.
- (b) An applicant shall demonstrate that, during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable data are available to the Department, at least 64% of the total number of hospice days of care provided to all of the clients of the applicant hospice were provided in a private residence.
- (c) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.
- (6) AN APPLICANT PROPOSING TO ACQUIRE NURSING HOME/HLTCU BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO BARIATRIC PATIENTS SHALL MEET THE FOLLOWING:
  - (a) THE FACILITY SHALL NOT BE AWARDED MORE THAN 10 BEDS.
- THE FACILITY MAY PLACE BEDS THROUGHOUT THE FACILITY FOR A FLEXIBLE AND SEAMLESS INCLUSIVE RESIDENT DESIGN.
- THE PROPOSED BEDS SHALL HAVE ADEQUATE ACCESS TO AN OUTDOOR OR INDOOR AREA FOR ACTIVITIES WITH APPROPRIATE EQUIPMENT.

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CON Review Standards for Nursing Home and HLTCU Beds For Proposed Action 3-16-17 Commission Meeting HIGHLIGHTED Text - Proposed edits

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(d)	THE PHYSICAL ENVIR	ONMENT OF	ANY UNIT	<b>CONTAINING</b>	BARIATRIC E	BEDS SHAL	L BE
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- (e) THE BEDS SHALL HAVE AVAILABLE SPECIALTY EQUIPMENT TO ASSIST STAFF IN
- (f) THE BEDS SHALL BE LOCATED ON A GROUND FLOOR AND EMERGENCY EGRESS WILL NOT REQUIRE STAIRWAYS OR ELEVATORS TO EXIT.
- (g) BEDS APPROVED UNDER THIS SUBSECTION SHALL NOT BE CONVERTED TO OR UTILIZED AS GENERAL NURSING HOME USE WITHOUT A CON FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS UNDER THE CON REVIEW STANDARDS,
- (i) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.
- (7) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to ventilator-dependent patients shall meet the following:
- (a) An applicant proposes a program for caring for ventilator-dependent patients in licensed nursing home beds.
  - (b) An application proposes no more than 40 beds that will be licensed as nursing home beds.
  - (c) The proposed unit will serve only ventilator-dependent patients.
- (d) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

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

- Sec. 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 Nursing Home and Hospital Long-term Care Unit Beds.
- (2) An applicant for beds from the statewide pool for special population groups allocated to religious shall agree that, if approved, the services provided by the specialized long-term care beds shall be delivered in compliance with the following term 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 95 percent or more. If this occupancy rate has not been met, the applicant shall delicense a number of beds necessary to result in a 95 percent occupancy based upon its average daily census for the third full year of operation.
- (3) An applicant for beds from the statewide pool for special population groups allocated to Alzheimer's disease shall agree that if approved:
- (a) The beds are part of a specialized program for Alzheimer's disease which will admit and treat only patients which require long-term nursing care and have been appropriately classified as a patient on the Global Deterioration Scale (GDS) for age-associated cognitive decline and Alzheimer's disease as a level 4 (when accompanied by continuous nursing needs), 5, or 6.
  - (b) The specialized program will participate in the state registry for Alzheimer's disease.
- (c) The specialized program shall be attached or geographically adjacent to a licensed nursing home and be no larger than 20 beds in size.
- (d) The proposed Alzheimer's unit shall have direct access to a secure outdoor or indoor area at the health facility, appropriate for unsupervised activity.
- (e) The Alzheimer's unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the Alzheimer's unit patients.
- (f) The physical environment of the Alzheimer's unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.
  - (g) Staff will be specially trained in Alzheimer's disease treatment.

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CON Review Standards for Nursing Home and HLTCU Beds For Proposed Action 3-16-17 Commission Meeting HIGHLIGHTED Text — Proposed edits CON-217 Page 30 of 34

- CON Review Standards for Nursing Home and HLTCU Beds For Proposed Action 3-16-17 Commission Meeting HIGHLIGHTED Text – Proposed edits

- (4) An applicant for beds from the statewide pool for special population groups allocated to hospice 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) An applicant shall maintain Medicare certification of the hospice program and shall establish and maintain the ability to provide, either directly or through contractual arrangements, hospice services as outlined in the Code of Federal Regulations, Title 42, Chapter IV, Subpart B, Part 418, hospice care.
- (b) The proposed project shall be designed to promote a home-like atmosphere that includes accommodations for family members to have overnight stays and participate in family meals at the applicant facility.
- (c) An applicant shall not refuse to admit a patient solely on the basis that he/she is HIV positive, has AIDS or has AIDS related complex.
- (d) An applicant shall make accommodations to serve patients that are HIV positive, have AIDS or have AIDS related complex in nursing home beds.
- (e) An applicant shall make accommodations to serve children and adolescents as well as adults in nursing home beds.
- (f) Nursing home beds shall only be used to provide services to individuals suffering from a disease or condition with a terminal prognosis in accordance with Section 21417 of the Code, being Section 333.21417 of the Michigan Compiled Laws.
- (g) An applicant shall agree that the nursing home beds shall not be used to serve individuals not meeting the provisions of Section 21417 of the Code, being Section 333.21417 of the Michigan Compiled Laws, unless a separate CON is requested and approved pursuant to applicable CON review standards.
- (h) An applicant shall be licensed as a hospice program under Part 214 of the Code, being Section 333.21401 et seq. of the Michigan Compiled Laws.
- (i) An applicant shall agree that at least 64% of the total number of hospice days of care provided by the applicant hospice to all of its clients will be provided in a private residence.
- (5) An applicant for beds from the statewide pool for special population groups allocated to ventilator-dependent 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) An applicant shall staff the proposed ventilator-dependent unit with employees that have been trained in the care and treatment of ventilator-dependent patients and includes at least the following:
- (i) A medical director with specialized knowledge, training, and skills in the care of ventilator-dependent patients.
  - (ii) A program director that is a registered nurse.
- (b) An applicant shall make provisions, either directly or through contractual arrangements, for at least the following services:
  - (i) respiratory therapy.
  - (ii) occupational and physical therapy.
  - (iii) psychological services.
  - (iv) family and patient teaching activities.
- (c) 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 ventilator-dependent unit. At a minimum, the criteria shall address the amount of mechanical ventilatory dependency, the required medical stability, and the need for ancillary services.
  - (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.
- (iv) Patient rights and responsibilities in accordance with Sections 20201 and 20202 of the Code, being Sections 333.20201 and 333.20202 of the Michigan Compiled Laws.
  - (v) The type of ventilatory equipment to be used on the unit and provisions for back-up equipment.

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- (d) An applicant shall establish and maintain an organized infection control program that has written policies for each of the following:
- (i) use of intravenous infusion apparatus, including skin preparation, monitoring skin site, and frequency of tube changes.
  - (ii) placement and care of urinary catheters.
  - (iii) care and use of thermometers.
  - (iv) care and use of tracheostomy devices.
  - (v) employee personal hygiene.
  - (vi) aseptic technique.
  - (vii) care and use of respiratory therapy and related equipment.
  - isolation techniques and procedures. (viii)
- (e) An applicant shall establish a multi-disciplinary infection control committee that meets on at least a monthly basis and includes the director of nursing, the ventilator-dependent unit program director, and representatives from administration, dietary, housekeeping, maintenance, and respiratory therapy. This subsection does not require a separate committee, if an applicant organization has a standing infection control committee and that committee's charge is amended to include a specific focus on the ventilator-dependent unit.
- (f) The proposed ventilator-dependent unit shall have barrier-free access to an outdoor area in the immediate vicinity of the unit.
- (g) An applicant shall agree that the beds will not be used to service individuals that are not ventilator-dependent unless a separate CON is requested and approved by the Department pursuant to applicable CON review standards.
- (h) An applicant shall provide data to the Department that evaluates the cost efficiencies that result from providing services to ventilator-dependent patients in a hospital.
- (6) An applicant for beds from the statewide pool for special population groups allocated to TBI/SCI patients shall agree that if approved:
- (a) An applicant shall staff the proposed unit for TBI/SCI patients with employees that have been trained in the care and treatment of such individuals and includes at least the following:
- (i) A medical director with specialized knowledge, training, and skills in the care of TBI/SCI patients.
  - (ii) A program director that is a registered nurse.
  - (iii) Other professional disciplines required for a multi-disciplinary team approach to care.
- An applicant shall establish and maintain written policies and procedures for each of the (b) following:
- (i) Patient admission criteria that describe minimum and maximum characteristics for patients appropriate for admission to the unit for TBI/SCI patients. At a minimum, the criteria shall address the required medical stability and the need for ancillary services, including dialysis services.
- (ii) The transfer of patients requiring care at other health care facilities, including a transfer agreement with one or more acute-care hospitals in the region to provide emergency medical treatment to any patient who requires such care.
- (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, including support services to be provided by transitional living programs or other outpatient programs or services offered as part of a continuum of care to TBI patients by the applicant.
- (iv) Utilization review, which shall consider the rehabilitation necessity for the service, quality of patient care, rates of utilization and other considerations generally accepted as appropriate for review.
- (v) Quality assurance and assessment program to assure that services furnished to TBI/SCI patients meet professional 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 TBI patient receiving such services.

- (7) An applicant for beds from the statewide pool for special population groups allocated to behavioral patients shall agree that if approved:
- (a) An applicant shall staff the proposed unit for behavioral patients with employees that have been trained in the care and treatment of such individuals and includes at least the following:
- (i) A medical director with specialized knowledge, training, and skills in the care of behavioral patients.
  - (ii) A program director that is a registered nurse.
  - (iii) Other professional disciplines required for a multi-disciplinary team approach to care.
- (b) 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 unit for behavioral patients.
- (ii) The transfer of patients requiring care at other health care facilities, including a transfer agreement with one or more acute-care hospitals in the region to provide emergency medical treatment to any patient who requires such care.
- (iii) Utilization review, which shall consider the rehabilitation necessity for the service, quality of patient care, rates of utilization and other considerations generally accepted as appropriate for review.
- (iv) quality assurance and assessment program to assure that services furnished to behavioral patients meet professional 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 behavioral patient receiving such services.
- (v) Orientation and annual education/competencies for all staff, which shall include care guidelines, specialized communication, and patient safety.
- (8) AN APPLICANT FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO BARIATRIC PATIENTS SHALL AGREE THAT IF APPROVED:
  - (a) THE FACILITY SHALL NOT BE AWARDED MORE THAN 10 BEDS.
- (b) THE FACILITY MAY PLACE BEDS THROUGHOUT THE FACILITY FOR A FLEXIBLE AND
- SEAMLESS INCLUSIVE RESIDENT DESIGN.
- (c) THE PROPOSED BEDS SHALL HAVE ADEQUATE ACCESS TO AN OUTDOOR OR INDOOR AREA FOR ACTIVITIES WITH APPROPRIATE EQUIPMENT.
- (d) THE PHYSICAL ENVIRONMENT OF ANY UNIT CONTAINING BARIATRIC BEDS SHALL BE DESIGNED TO FACILITATE VISITORS.
- (e) THE BEDS SHALL HAVE AVAILABLE SPECIALTY EQUIPMENT TO ASSIST STAFF IN PROVIDING CARE.
- (f) THE BEDS SHALL BE LOCATED ON A GROUND FLOOR AND EMERGENCY EGRESS
- WILL NOT REQUIRE STAIRWAYS OR ELEVATORS TO EXIT.
- (g) THE BEDS SHALL BE ESTABLISHED IN EITHER SINGLE OR DOUBLE OCCUPANCY
- ROOMS, THERE SHALL BE NO ROOMS WITH MORE THAN TWO BEDS.
- (i) ALL BEDS APPROVED PURSUANT TO THIS SUBSECTION SHALL BE DUALLY CERTIFIED FOR MEDICARE AND MEDICAID.

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

- Sec. 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.

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CON Review Standards for Nursing Home and HLTCU Beds
For Proposed Action 3-16-17 Commission Meeting
HIGHLIGHTED Text – Proposed edits

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- (4) Projects proposed under Section 7 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.
- (5) These CON review standards supercede and replace the CON Review Standards for Nursing Home and Long-term Care Unit Beds--Addendum for Special Population Groups approved by the Commission on DECEMBER 11, 2014 and effective on MARCH 20, 2015.

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#### MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

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# CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR BONE MARROW TRANSPLANTATION (BMT) SERVICES

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

#### Section 1. Applicability

- Sec. 1. (1) These standards are requirements for the approval to initiate or acquire BMT services under Part 222 of the Code. BMT services are a covered clinical service pursuant to 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(C) of the Code, being Section 333.22225(2)(C) of the Michigan Compiled Laws.
- (2) A BMT service listed on the Department inventory that is located at a hospital site and initially does not perform both allogeneic and autologous procedures shall not be required to obtain separate CON approval to begin performing both autologous and allogeneic BMT procedures.
- (3) An existing BMT service that performs only adult procedures shall require separate CON approval in order to perform pediatric procedures. An existing BMT service that performs only pediatric procedures shall require separate CON approval in order to perform adult procedures.

#### Section 2. Definitions

Sec. 2. (1) As used in these standards:

- (a) "Adult" means an individual age 18 or older.
- (b) "Allogeneic" means transplantation between genetically non-identical individuals of the same species.
  - (c) "Autologous" means transplantation in which the donor and recipient are the same individual.
- (d) "Bone marrow transplantation service" or "BMT service" means the transplantation of proliferating hematopoietic stem cells essential to the survival of a patient derived from the bone marrow, the peripheral circulation, cord blood, or any other source.
- (e) "Cancer hospital" means a hospital that is a Comprehensive Cancer Center designated by the National Cancer Institute or operates a Comprehensive Cancer Center as an affiliate of a Michigan university that is designated as a Comprehensive Cancer Center by the National Cancer Institute.
- (f) "Certificate of Need Commission" or "CON Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.
- (h) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.
  - (i) "Department" means the Michigan Department of Health AND HUMAN SERVICES (MDHHS).
- (j) "Department inventory of BMT services" means the list maintained by the Department of: (i) the bone marrow transplantation services operating pursuant to a valid CON issued under Part 222 or former Part 221; (ii) operating BMT services for which the operation of that service did not require a CON; and (iii) BMT services that are not yet operational but have a valid CON issued under Part 222. The list shall inventory adult and pediatric services separately and shall specify the site at which the BMT service is authorized.
- (k) "Existing BMT service," for purposes of Section 3(5) of these standards, means any of the following: (i) a BMT service listed on the Department inventory, (ii) a proposed BMT service under appeal from a final decision of the Department, or (iii) a proposed BMT service that is part of a completed

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CON Review Standards for BMT Services

**DRAFT CHANGES & UPDATE-NEEDED UPON FINALIZATION** 

For Review at 3-16-17 CON Commission Meeting

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application under Part 222 (other than the application under review) for which a proposed decision has been issued and which is pending final decision.

- (I) "Health service area" or "HSA" means the geographic area set forth in Appendix A.
- (m) "Initiate" or "implement" means the performance of the first transplant procedure. The term of an approved CON shall be 18 months or the extended period established by Rule 325.9403(2).
- (n) "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.
- (o) "Licensed site" means the location of the hospital authorized by license and listed on that licensee's certificate of licensure.
- (p) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396g and 1396i to 1396u.
- (q) "Pediatric" means any patient 20 years of age or less or any patient with congenital conditions or diseases for which BMT is a treatment.
  - (r) "Planning area" means THE GROUPS OF COUNTIES SHOW IN APPENDIX A.
- "Qualifying project" means each application in a comparative group that 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.
- (t) "Survival rate" means the rate calculated using the Kaplan-Meier technique and the following: (i) the date of transplantation (or, if more than one transplant is performed, the date of the first transplant) must be the starting date for calculation of the survival rate; (ii) for those dead, the date of death is used, if known. If the date of death is unknown, it must be assumed as 1 day after the date of the last ascertained survival; (iii) for those who have been ascertained as surviving within 60 days before the fiducial date (the point in time when the facility's survival rates are calculated and its experience is reported), survival is considered to be the date of the last ascertained survival, except for patients described in subsection (v); (iv) any patient who is not known to be dead, but whose survival cannot be ascertained to a date that is within 60 days before the fiducial date, must be considered as "lost to follow up" for the purposes of the survival rate calculation; (v) any patient transplanted between 61 and 120 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained for at least 60 days before the fiducial date. Any patient transplanted within 60 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained on the fiducial date; and (vi) the survival analyses must use the assumption that each patient in the "lost to follow up" category died 1 day after the last date of ascertained survival. However, an applicant may submit additional analyses that reflect each patient in the "lost to follow up" category as alive at the date of the last ascertained survival.
- (u) "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.
  - (2) The definitions of Part 222 shall apply to these standards.

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\_(i) \_ planning area one that includes the counties in health service areas 1, 2, 5, and 6, and the following counties in health service area 7: Alcona, Alpena, Cheboygan, Crawford, Montmorency, Oscoda, Otsego, and Presque Isle; or¶

. (ii) . planning area two that includes the counties in health service areas 3, 4, and 8, and the following counties in health service area 7: Antrim, Benzie, Charlevoix, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, and Wexford.

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#### Section 3. Requirements to initiate a BMT service

Sec. 3. Initiate a BMT service means to begin operation of a BMT service at a site that does not provide either adult or pediatric BMT services and is not listed on the Department inventory as of the date an application is submitted to the Department. The term includes an adult service that is proposing to provide a pediatric BMT service, and a pediatric service that is proposing to provide an adult BMT service. The term does not include beginning operation of a BMT service by a cancer hospital which acquires an existing BMT service provided that all of the staff, services, and programs required under Section 3(3) are to be provided by the cancer hospital and/or by the hospital from which the BMT service is being acquired. An applicant proposing to initiate a BMT service shall demonstrate the following requirements, as applicable to the proposed project.

- (1) An applicant shall specify in the application whether the proposed service will perform either or both adult and pediatric BMT procedures.
  - (2) An applicant shall specify the licensed site at which the BMT service will be provided.
- (3) An applicant proposing to initiate either an adult or pediatric BMT service shall demonstrate that the licensed site at which the transplants will be offered provides each of the following staff, services, and programs:
  - (a) operating rooms.
- (b) continuous availability, on-site or physically connected, either immediate or on-call, of CT scanning, magnetic resonance imaging, ultrasound, angiography, and nuclear medicine services.
  - (c) dialysis.
  - (d) inpatient-outpatient social work.
  - (e) inpatient-outpatient psychiatry/psychology.
  - (f) clinical research.
  - (g) a microbiology and virology laboratory.
- (h) a histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics, or an equivalent organization, either on-site or through written agreement.
  - (i) a hematopathology lab capable of performing cell phenotype analysis using flow cytometry.
- (j) a clinical chemistry lab with the capability to monitor antibiotic and antineoplastic drug levels, available either on-site or through other arrangements that assure adequate availability.
  - (k) other support services, as necessary, such as physical therapy and rehabilitation medicine.
- (l) continuous availability of anatomic and clinical pathology and laboratory services, including clinical chemistry, and immuno-suppressive drug monitoring.
  - (m) continuous availability of red cells, platelets, and other blood components.
- (n) an active medical staff that includes, but is not limited to, the following board-certified or boardeligible specialists. For an applicant that is proposing to perform pediatric transplant procedures, these specialists shall be board-certified or board-eligible in the pediatric discipline of each specialty.
  - (i) anesthesiology.
  - (ii) cardiology.
  - (iii) critical care medicine.
  - (iv) gastroenterology.
  - (v) general surgery.
  - (vi) hematology.
  - (vii) infectious diseases.
  - (viii) nephrology.
  - (ix) neurology.
  - (x) oncology.
  - (xi) pathology, including blood banking experience.
  - (xii) pulmonary medicine.

- (xiii) radiation oncology.
- (xiv) radiology.
- (xv) urology.
- (o) One or more consulting physicians who are board-certified or board-eligible in each of the following specialties. For an applicant proposing to perform pediatric BMT procedures, these specialists shall have specific experience in the care of pediatric patients.
  - (i) dermatology.
  - (ii) immunology.
  - (iii) neurosurgery.
  - (iv) orthopedic surgery.
- (p) A TRANSPLANT TEAM COORDINATOR ON-SITE, WHO HAS EXPERIENCE IN EVALUATING PRE AND POST BMT PATIENTS
- (q) NURSES WITH SPECIALIZED TRAINING IN PEDIATRIC AND/OR ADULT, AS APPROPRIATE, BMT HEMATOLOGY/ONCOLOGY PATIENT CARE, ADMINISTRATION OF CYTOTOXIC THERAPIES, MANAGEMENT OF INFECTIONS COMPLICATIONS ASSOCIATED WITH HOST-DEFENSE MECHANISMS, ADMINISTRATION OF BLOOD COMPONENTS, THE HEMODYNAMIC SUPPORT OF THE TRANSPLANT PATIENT AND MANAGING IMMUNOSUPPORESSED PATIENTS.
- (r) A PHARMACIST EXPERIENCED WITH THE USE OF CYTOTOXIC THERAPIES, USE OF BLOOD COMPONENTS, THE HEMODYNAMIC SUPPORT OF THE TRANSPLANT PATIENT, AND THE MANAGEMENT OF IMMUNO-SUPPRESSED PATIENTS.
- (s) A PROTECTIVE ENVIRONMENTAL INPATIENT UNIT FOR IMMUNO-SUPPRESSED PATIENTS THAT HAS AN ISOLATION POLICY, AND INFECTION CONTROL PLAN SECIFIC TO THAT UNIT, AND AIR HANDLING CAPABLE OF PREVENTING NOSOCOMIAL INFECTIONS DISSEMINATED FROM CENTRAL HEATING AND COOLING SYSTEMS AND AMBIENT AIR.
- (4) An applicant must provide an implementation plan for the proposed BMT service. "Implementation plan" means a plan that documents how a proposed BMT service will be initiated within the time period specified in these standards or the CON rules. At a minimum, the implementation plan shall identify:
- (a) each component or activity necessary to begin performing the proposed BMT service including, but not limited to, the development of physical plant requirements, such as an intensive care unit capable of treating immuno-suppressed patients, equipment acquisitions, and recruitment and employment of all physician and support staff;
  - (b) the time table for completing each component or activity specified in subsection (a); and
- (c) if the applicant previously has been approved for a BMT service for which either the CON expired or the service did not perform a transplant procedure during any consecutive 12-month period, what changes have or will be made to ensure that the proposed service can be initiated and provided on a regular basis.
- (5) THE APPLICANT MUST BE AN ACADEMIC MEDICAL CENTER AT THE TIME OF APPLICATION AND MEET ALL OF THE FOLLOWING CRITERIA:
- (a) THE APPLICANT HOSPITAL IS ORGANIZATIONALLY AND ADMINISTRATIVELY INTEGRATED WITH A MEDICAL SCHOOL.
- (b) THE APPLICANT HOSPITAL IS THE PRINCIPAL SITE FOR THE EDUCATION OF BOTH MEDICAL STUDENTS (UNDERGRADUATES) AND POSTGRADUATE MEDICAL SPECIALTY TRAINEES (E.G., RESIDENTS OR INTERNS) FROM THE MEDICAL SCHOOL IN 5(a) OF THIS SECTION
- (c) AT THE TIME OF APPLICATION, THE APPLICANT HOSPITAL IS CONDUCTING ACADEMIC HUMAN SUBJECTS RESEARCH UNDER MULTIPLE APPROVED PROTOCOLS INOLVING PATIENTS OF THE HOSPITAL.

Commented [A2]: (p)(q)(r) and (s) are pulled from comparative review.

Commented [A3]: Joint Commission International definition: http://www.jointcommissioninternational.org/assets/3/7/ER\_Hospital\_AMC.pdf

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CON Review Standards for BMT Services

**DRAFT CHANGES & UPDATE-NEEDED UPON FINALIZATION** 

For Review at 3-16-17 CON Commission Meeting

CON-229

Page 4 of 12

- (6)(a) An applicant proposing to initiate an adult BMT service shall project that at least 30 transplants, of which at least 10 are allogeneic transplant procedures, will be performed in the third 12-months of operation.
- (b) An applicant proposing to initiate a pediatric BMT service shall project that at least 10 transplants, of which 5 are allogeneic transplant procedures, will be performed in the third 12-months of operation.
- (c) An applicant proposing to initiate both an adult and a pediatric BMT service shall specify whether patients age 18-20 are included in the projection of adult procedures required pursuant to subsection (a) or the projection of pediatric procedures required pursuant to subsection (b). An applicant shall not include patients age 18-20 in both adult and pediatric projections required pursuant to subsections (a) and (b).
- (7) THE APPLICANT SHALL PROVIDE THE FOLLOWING SERVICES WITH AN APPROVED CERTIFICATE OF NEED AND AT THE TIME OF APPLICATION MUST BE IN COMPLIANCE WITH ALL PROJECT DELIVERY REQUIRMENTS INCLUDING BUT NOT LIMITED TO VOLUME REQUIREMENTS
- (a) Megavoltage radiation therapy services, either on-site or physically connected, with a nominal beam energy of at least 6 MEV, including the capability to perform total body irradiation.
  - (b) HEART, LUNG AND LIVER TRANSPLANTATION SERVICES.
  - SURGICAL SERVICES.
- (8) An applicant shall demonstrate that the licensed site at which the proposed BMT service is proposed has an institutional review board.
- (9) An applicant proposing to initiate a pediatric BMT service shall demonstrate that the licensed site at which the pediatric transplant procedures will be performed has each of the following:
  - (a) a designated pediatric inpatient oncology unit.
  - (b) a pediatric inpatient intensive care unit.
- (c) membership status in either the Pediatric Oncology Group (POG) or the Children's Cancer Group (CCG).
  - (d) a pediatric tumor board that meets on a regularly scheduled basis.
  - (e) family support group services, provided either directly or through written agreements.
  - (f) a pediatric cancer program with the following staff:
- (i) a director who is either a board-certified immunologist who has specific training and experience in BMT or a board-certified pediatric hematologist/oncologist.
  - (ii) nurses with training and experience in pediatric oncology.
  - (iii) social workers with training and experience in pediatric oncology.
  - (iv) pediatric psychologists.
  - (v) child life specialists.
- (10)(a) An applicant proposing to initiate either a new adult or pediatric BMT service shall submit, in its application, a written consulting agreement with an existing BMT service. The written consulting agreement must be with an existing in-state or out-of-state Foundation for the Accreditation of Cellular Therapy (FACT) accredited transplant unit that performs both allogenic and autologous transplants for either adult and/or pediatrics. The terms of the agreement and the roles and responsibilities of both the existing and proposed service shall include at least the following:
- (i) The term of the written consulting agreement is no less than 36 months after the proposed service begins to perform BMT procedures.
- (ii) One or more representatives of the existing BMT service have been designated as staff responsible for carrying out the roles and responsibilities of the existing service.
- (iii) The existing service shall evaluate and make recommendations to the proposed service on policies and procedures, including time tables, for at least each of the following:
  - (A) nursing services.

For Review at 3-16-17 CON Commission Meeting

BMT services exceeding the need for each specific planning (b) An applicant shall demonstrate that the number of existing pediatric BMT services does not exceed two (2) pediatric BMT services in planning area one identified in Section 2(1)(t)(i) or one (1) pediatric BMT service in planning area two identified in Section 2(1)(t)(ii) and that approval of the proposed application will not result in the total number of

pediatric BMT services exceeding the need for each specific

Deleted: (5)(a) An applicant shall demonstrate that the number of existing adult BMT services does not exceed three

(3) adult BMT services in planning area one identified in

two identified in Section 2(1)(t)(ii) and that approval of the

Section 2(1)(t)(i) or one (1) adult BMT service in planning area

proposed application will not result in the total number of adult

<mark>planning area.</mark>¶

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CON Review Standards for BMT Services **DRAFT CHANGES & UPDATE-NEEDED UPON FINALIZATION** 

CON-229

- (B) infection control.
- (C) nutritional support.
- (D) staff needs and training.
- (E) inpatient and outpatient medical coverage.
- (F) transfusion and blood bank policies.
- (G) transplant treatment protocols.
- (H) hematopoiesis laboratory services and personnel.
- (I) data management.
- (J) quality assurance program.
- (iv) Specify a schedule of site visits by staff of the existing BMT service that, at a minimum, includes:
  - (A) 3 visits during the first 12-months of operation of the proposed service.
- (B) 3 visits during each the second 12-months and third 12-months of operation of the proposed service.
- (v) Specify that the purpose of the site visits required by subdivision (iv) is to assess the proposed service and make recommendations related to quality assurance mechanisms of the proposed service, including at least each of the following:
  - (A) a review of the number of patients transplanted.
  - (B) transplant outcomes.
- (C) all infections requiring treatment or life-threatening toxicity, defined for purposes of this agreement as National Cancer Institutes grade #3 or greater toxicity, excluding hematological toxicity.
  - (D) all deaths occurring within 100 days from transplant.
  - (E) each of the requirements of subdivision (iii).
- (vi) Specify that a written report and minutes of each site visit shall be completed by the existing BMT service and sent to the proposed service within 2 weeks of each visit, and that copies of the reports and minutes shall be available to the Department upon request. At a minimum, the written report shall address each of the items in subdivision (v).
- (vii) Specify that the existing BMT service shall notify the Department and the proposed service immediately if it determines that the proposed service may not be in compliance with any applicable quality assurance requirements, and develop jointly with the proposed service a plan for immediate remedial actions.
- (viii) Specify that the existing BMT service shall notify the Department immediately if the consulting agreement required pursuant to these standards is terminated and that the notification shall include a statement describing the reasons for the termination.
- (b) For purposes of subsection (10), "existing BMT service" means a service that meets all of the following:
- (i) currently is performing and is FACT accredited in, the types of transplants (allogeneic and autologous; adult or pediatric) proposed to be performed by the applicant:
  - (ii) currently is certified as a National Marrow Donor Program; and
  - (iii) is located in the United States.
- (c) An applicant shall document that the existing BMT service meets the requirements of subsection (b).

#### Section 4. Requirements for approval – acquisition of a BMT service by a cancer hospital

- Sec 4. Acquisition of a BMT service means the acquisition (including purchase, lease, donation, or other arrangement) of an existing BMT service. An applicant proposing to acquire an existing BMT service shall demonstrate the following, as applicable to the proposed project.
  - (1) The applicant meets all of the requirements of this subsection:
- (a) The total number of BMT services is not increased in the planning area as the result of the acquisition.

Deleted: and shall not be required to be in compliance with Section 3(5) and the department inventory.

- (b) As part of the acquisition of the BMT service, the acquisition or replacement of the cancer hospital, or for any other reasons, the location of the BMT service shall be located at its prior location or in space within the licensed cancer hospital site.
  - (c) The applicant is a cancer hospital as defined by these standards.
- (d) The applicant demonstrates that it meets, directly or through arrangements with the hospital from which it acquires the BMT service, the requirements set forth under Section 3(3), (6), (7), and (8), as applicable.
- (e) The applicant agrees to either have a written consulting agreement as required by Section 3(10) or obtain a determination by the Department that such an agreement is not required because the existing BMT staff, services, and program substantially will continue to be in place after the acquisition.
- (f) The applicant agrees and assures to comply, either directly or through arrangements with the hospital from which it acquires the BMT service, with all applicable project delivery requirements.

#### 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 BMT 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 key staff or other aspects of the BMT service that may affect its ability to comply with these standards.
- (2) Compliance with the following quality assurance requirements, as applicable, no later than the date the first BMT procedure, allogeneic or autologous, is performed:
- (a) An applicant shall establish and maintain, either on-site or through written agreements, all of the following:
- (i) 24-hour blood bank support, including pheresis capability, irradiated blood, products suitable for cytomegalovirus-negative transplants, and blood component therapy.
  - (ii) a cytogenetics and/or molecular genetic laboratory.
- (iii) a processing and cryopreservation laboratory that meets the standards of the FACT or an equivalent organization.
- (iv) a histocompatibility laboratory that has the capability of DNA-based HLA-typing and meets the standards of the American Society for Histocompatibility and Immunogenetics or an equivalent organization.
- (v) anatomic and clinical pathology with competency in interpreting pathologic findings related to graft-v-host disease (programs performing allogeneic transplants) and other opportunistic infections in immuno-compromised hosts (programs performing allogeneic and autologous transplants).
  - (vi) therapeutic drug monitoring.
- (b) An applicant shall establish and maintain, at the licensed hospital site at which the transplants are performed, both of the following:
- (i) a protective environmental BMT inpatient unit for immuno-suppressed patients that has an isolation policy, an infection control plan specific to that unit, and an air handling system capable of preventing nosocomial infections disseminated from central heating and cooling systems and ambient air.
  - (ii) a specialized intensive care unit capable of treating immuno-suppressed neutropenic patients.
- (c) An applicant shall establish and maintain written policies related to outpatient care for BMT patients, including at least the following:
  - (i) the ability to evaluate and provide treatment on a 24-hour basis.

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- . (2) An applicant approved for and holding a CON for BMT services under this section prior to the effective date of this revision of the BMT standards, September 29, 2014, shall apply to reacquire the BMT service, and the acquired BMT service shall be accountable under these revised standards.
- . (3) Applicants proposing to acquire an existing BMT service under this section shall not be subject to comparative review.

#### Section 5. Review standards for comparative reviews¶

- Sec. 5. (1) Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and reviewed comparatively with other applications in accordance with the CON rules applicable.
- (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) being Section 333. 22225(1) of the Michigan Compiled Laws, and which have the highest number of points when the results of subsection (2) 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, taken together, do not exceed the need, as defined in Section 22225(1) of the Code, being Section 333. 22225(1) of the Michigan Compiled Laws, 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 CON administrative unit of the Department responsible for administering the CON program when an application is submitted.
- . (3)(a) . A qualifying project will have points awarded based on the straight-line distance to the nearest existing BMT service of the type applied for (adult or pediatric), as shown in the following schedule:¶

	Straight-line Distance Points
	to Nearest BMT Service Awarded¶
•	<mark><object></object></mark> ¶
	<75 miles0¶
	75 – 150 miles1¶
	>150 miles 2

- (b) A qualifying project will have up to 4 points awarded based on the percentage of the medical/surgical indigent volume at the licensed site at which the proposed BMT service will be provided in accordance with the following:
- . (i) . For each applicant in the same comparative group, determine the medical/surgical indigent volume. Determine the licensed site that has the highest indigent volume in the same comparative group. Divide the medical/surgical indigent volume for that licensed site by 4.0. The result is the indigent volume factor rounded to the nearest whole number

- (ii) nurses experienced in the care of BMT patients.
- (iii) a designated outpatient area for patients requiring long-duration infusions or the administration of multiple medications or blood product transfusions.
- (d) A BMT service shall establish and maintain a dedicated transplant team that includes at least the following staff:
- (i) a transplant team leader, who is a physician that is board-certified in at least one of the following specialties: hematology, medical oncology, immunology, or pediatric hematology/oncology, as appropriate, and has had either at least one year of specific clinical training or two years of experience, both inpatient and outpatient, as an attending physician principally responsible for the clinical management of patients treated with hematopoietic transplantation. The team leader's experience shall include the clinical management of patients receiving an allogeneic transplant. The responsibilities of the transplant team leader shall include overseeing the medical care provided by attending physicians, reporting required data to the Department, and responsibility for ensuring compliance with the all applicable project delivery requirements.
- (ii) one or more attending physicians with specialized training in pediatric and/or adult BMT, as appropriate. At least one attending physician shall have specialized training in allogeneic transplantation, adult or pediatric, as appropriate. An attending physician shall be board-certified or board-eligible in hematology, medical oncology, immunology, or pediatric hematology/oncology, as appropriate.
- (iii) on-site availability of board-certified or board-eligible consulting physicians, adult and/or pediatric, as appropriate, in at least the following specialities: cardiology, gastroenterology nephrology, psychiatry, pulmonary medicine, and critical care medicine.
- (iv) on-site availability of board-certified or board-eligible consulting physicians in the following areas: anatomic pathology with competence in graft versus host disease (services performing allogeneic transplants) and other opportunistic diseases (services performing allogeneic and autologous transplants), infectious diseases with experience in immuno-compromised hosts, and radiation oncology with experience in total body irradiation.
- (v) a transplant team coordinator, who shall be responsible for providing pre-transplant patient evaluation and coordinating treatment and post-transplant follow-up and care.
- (vi) a nurse to patient ratio necessary to provide care consistent with the severity of a patient's clinical status.
- (vii) nurses with specialized training in pediatric and/or adult, as appropriate, BMT, hematology/oncology patient care, administration of cytotoxic therapies, management of infectious complications associated with compromised host-defense mechanisms, administration of blood components, the hemodynamic support of the transplant patient, and managing immuno-suppressed patients.
- (viii) a pharmacist experienced with the use of cytotoxic therapies, use of blood components, the hemodynamic support of the transplant patient, and the management of immuno-suppressed patients.
- (ix) dietary staff capable of providing dietary consultations regarding a patient's nutritional status, including total parenteral nutrition.
  - (x) designated social services staff.
  - (xi) designated physical therapy staff.
  - (xii) data management personnel designated to the BMT service.
  - (xiii) for an applicant performing pediatric BMT, a child-life specialist.
- (e) In addition to the dedicated transplant team required in subsection (d), an applicant's staff shall include a patient ombudsman, who is familiar with the BMT service, but who is not a member of the transplant team.
- (f) An applicant shall develop and maintain patient management plans and protocols that include the following:
  - (i) therapeutic and evaluative procedures for the acute and long-term management of a patient.
- (ii) patient management and evaluation during the waiting, in-hospital and immediate postdischarge phases of the service.
- (iii) long-term management and evaluation, including education of the patient, liaison with the patient's attending physician, and the maintenance of active patient records for at least 5 years.

- (iv) IRB approval of all clinical research protocols, or if transplantation does not require an IRBapproved clinical research protocol, written policies and procedures that include at least the following: donor, if applicable, and recipient selection, transplantation evaluations, administration of the preparative regimen, post-transplantation care, prevention and treatment of graft-versus-host disease, and follow-up care.
  - (g) An applicant shall establish and maintain a written quality assurance plan.
- (h) An applicant shall implement a program of education and training for nurses, technicians, service personnel, and other hospital staff.
- (i) An applicant shall participate actively in the education of the general public and the medical community with regard to BMT, and make donation literature available in public areas of the institution.
- (j) An applicant shall establish and maintain an active, formal multi-disciplinary research program related to the proposed BMT service.
- (k) An applicant shall operate, either on-site or under its direct control, a multi-disciplinary selection committee which includes, but is not limited to, a social worker, a mental health professional, and physicians experienced in treating BMT patients.
- (I) A pediatric BMT service shall maintain membership status in the Children's Oncology Group (COG).
- (m) For purposes of evaluating subsection (2), except subdivision (k), the Department shall consider it prima facie evidence as to compliance with the applicable requirements if an applicant documents that the BMT service is accredited by the National Marrow Donor Program (NMDP) or the Foundation for the Accreditation of Cell Therapy (FACT).
  - (3) Compliance with the following access to care requirements:
- (a) The BMT service shall accept referrals for BMT services from all appropriately licensed health care practitioners
- (b) The BMT 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 BMT service shall not deny BMT services to any individual based on ability to pay or source of payment.
- (d) The operation of and referral of patients to the BMT 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) An adult BMT service shall perform at least 30 transplants, of which at least 10 are allogeneic transplants, in the third 12-months of operation and annually thereafter.
- (b) A pediatric BMT service shall perform at least 10 transplants, of which at least 5 are allogeneic transplants, in the third 12-months of operation. After the third 12-months of operation, an applicant shall perform at least 30 pediatric transplants in any 36-month consecutive period, with no fewer than 5 allogeneic transplants in any 12-month period, beginning with the third 12-months of operation, and thereafter
- (c) A BMT service that performs both adult and pediatric BMT shall specify whether each patient age 18-20 is included in the category of adult procedures or the category of pediatric procedures. An applicant shall determine for each patient age 18-20 whether to record that patient as an adult or a pediatric procedure, but an applicant shall record each patient age 18-20 in only 1 category.
- (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, demographic and diagnostic information, primary and secondary diagnoses, whether the transplant procedure was a first or repeat transplant procedure, 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 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. In addition, an applicant shall report at least the following data for each patient:

- (i) disease type.
- (ii) transplant type, i.e., related allogeneic, unrelated allogeneic, and autologous.
- (iii) source of hematopoietic stem cell, i.e., bone marrow, peripheral circulation, cord blood, etc.
- (iv) patient age, i.e., adult or pediatric as defined by these standards.
- (v) data on 100-day, 6-month, 1-year, 2-year, and 5-year survival rates.
- (vi) relapse rates at 6-months, 1-year, and 5-years post-transplant.
- (vii) median follow-up, and patients lost-to-follow-up.
- (viii) cause(s) of death, if applicable.
- (ix) additional summary information, as applicable.

An applicant annually shall report for its BMT service annual and cumulative survival rates by type of transplant performed reported in actual number of transplants by disease category, transplant type, i.e., related allogeneic, unrelated allogeneic, and autologous; source of hematopoietic stem cell; patient age, i.e., adult or pediatric, as defined by these standards; and relapse rates at 100-days, 6-months, one year, and five years post-transplant. For purposes of these standards, procedure-related mortality is defined as death occurring within 100 days from BMT.

- (e) The applicant shall maintain an organized institutional transplant registry for recording ongoing information on its patients being evaluated for transplant and on its transplant recipients and shall participate in the national and international registries applicable to the BMT service.
- (f) The BMT service shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules. A BMT service that initially does not perform both allogeneic and autologous procedures also shall notify the Department when it begins to perform autologous procedures.
- (g) An applicant shall notify the Department immediately if the consulting agreement required pursuant to Section 3(10) of these standards is terminated prior to the end of the first 36-months of operation of the BMT service. The notification shall include a statement describing the reasons for the termination. An applicant shall have 30 days following termination of that agreement to enter into a written consulting agreement that meets the requirements of Section 3(10). An applicant shall provide the Department with a copy of that written consulting agreement.
- (h) The Department may use the information provided pursuant to Section 3(10) of these standards in evaluating compliance with the requirements of this section.
- (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. Documentation of projections

Sec. 8. An applicant required to project volumes of service under Section 3 shall specify how the volume projections were developed. The applicant shall use relevant and unduplicated data for patients in the same planning area as the proposed BMT service, which are verifiable from the most recent statewide tumor registry. The applicant shall only include new cancer cases that are appropriate for referral for BMT services and from the age grouping of patients based on the type of service to be offered. This specification of projections shall include an assessment of the accuracy of projections, and of the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

#### Section 9. Department Inventory of BMT Services

Sec. 9. The Department shall maintain, and provide on request, a listing of the Department Inventory of BMT services.

Section 10. Effect on prior CON Review Standards; comparative reviews

Sec. 10. (1) These CON review standards supersede and replace the CON Review Standards for Extrarenal Organ Transplantation Services pertaining to BMT services approved by the CON Commission on JUNE 12, 2014 and effective on SEPTEMBER 29, 2014.

(2) Projects reviewed under these standards shall NOT be subject to comparative reviewe.

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CON-229

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### APPENDIX A

Counties assigned to each PLANNING AREAS are as follows:

PLANNING AREA,	COUNTIES			Deleted: HEALTH SERVICE
1	Livingston Macomb Wayne	Monroe Oakland	St. Clair Washtenaw	Deleted: AREA
_	0" .			

1	Livingston Macomb Wayne	Monroe Oakland	St. Clair Washtenaw
2	Clinton	Hillsdale	Jackson
	Eaton	Ingham	Lenawee
3	Barry Berrien Branch	Calhoun Cass Kalamazoo	St. Joseph Van Buren
4	Allegan	Mason	Newaygo
	Ionia	Mecosta	Oceana
	Kent	Montcalm	Osceola
	Lake	Muskegon	Ottawa
5	Genesee	Lapeer	Shiawassee
6	Arenac Bay Clare Gladwin Gratiot	Huron Iosco Isabella Midland Ogemaw	Roscommon Saginaw Sanilac Tuscola
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

#### CERTIFICATE OF NEED

## 1st Quarter Compliance Report to the CON Commission

October 1, 2016 through September 30, 2017 (FY 2017)

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**

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

Activity	1st Quarter	Year-to-Date
Approved projects requiring 1-year follow up	79	79
Approved projects contacted on or before anniversary date	38	38
Approved projects completed on or before 1-year follow up	48%	
CON approvals expired	8	8
Total follow up correspondence sent	122	122
Total approved projects still ongoing	396	

Compliance Report to CON Commission FY 2017 – 1<sup>st</sup> Quarter Page 2

<u>Compliance</u>: 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 Cardiac Catheterization Services and Megavoltage Radiation Therapy Services/Units utilizing 2015 CON Annual Survey data. The Department is in the process of evaluating annual survey data, review standard requirements, and CON approved facilities for these selected services to identify the facilities for compliance investigations. The summary reports are being submitted to the Commission under a separate cover. The finding of the statewide compliance reviews will be reported to the CON Commission at a later date.
- Crittenton Hospital Medical Center Facility self-reported to the Department that they utilized a temporary mobile CT scanner unit during the replacement of the two (2) fixed CT scanners at the hospital. The facility was required to establish an internal process to ensure that CON covered equipment receives approval prior to start of operations and involve management level education about CON processes and requirements. The facility submitted an amendment request to secure approval and paid a civil fine of \$6,000.
- Sparrow Carson City During an application review, it was noted that the facility had entered into a lease renewal for an existing fixed MRI unit without CON approval. The facility had to add the lease renewal to the current CON application as corrective action and paid a civil fine of \$5,500.

# CERTIFICATE OF NEED

# 1st Quarter Program Activity Report to the CON Commission

October 1, 2016 through September 30, 2017 (FY 2017)

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.

A officier.	1 <sup>st</sup> Quarter		Year-to-Date	
Activity	No.	Percent	No.	Percent
Letters of Intent Received	82	N/A	82	N/A
Letters of Intent Processed within 15 days	81	99%	81	99%
Letters of Intent Processed Online	82	100%	82	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.

A odinida.	1 <sup>st</sup> Quarter		Year-to-Date	
Activity	No.	Percent	No.	Percent
Applications Received	81	N/A	81	N/A
Applications Processed within 15 Days	79	98%	79	98%
Applications Incomplete/More Information Needed	60	74%	60	74%
Applications Filed Online*	77	100%	77	100%
Application Fees Received Online*	14	18%	14	18%

<sup>\*</sup> 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.

A 04::4	1 <sup>st</sup> Qua	1 <sup>st</sup> Quarter		-Date
Activity	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	42	100%	42	100%
Substantive Applications	26	100%	26	100%
Comparative Applications	0	N/A	0	N/A

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

Program Activity Report to CON Commission FY 2017 – 1<sup>st</sup> Quarter Page 2 of 2

## 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.

A a4::4	1 <sup>st</sup> Quarter		Year-to-Date	
Activity	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.

A a4::4	1 <sup>st</sup> Qua	rter	Year-to-	Date
Activity	Issued on Time Percent		Issued on Time	Percent
Amendments	17	100%	17	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	1 <sup>st</sup> Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

## **Other Measures**

Activity	1 <sup>st</sup> Qı	1 <sup>st</sup> Quarter		Year-to-Date	
Activity	No.	Percent	No.	Percent	
FOIA Requests Received	35	N/A	35	N/A	
FOIA Requests Processed on Time *	35	100%	35	100%	
Number of Applications Viewed Onsite	2	N/A	2	N/A	

FOIA – Freedom of Information Act.

<sup>\*</sup>Request processed within 5 days or an extension filed.

#### 2015 Megavoltage Radiation Therapy (MRT) – CON Statewide Compliance Review

As part of the Megavoltage Radiation Therapy (MRT) statewide compliance review, the Department looked at 68 facilities that have MRT services based on data reported in the 2015 Certificate of Need (CON) Annual Survey. The 68 facilities that we reviewed were approved under 7 different MRT review standards dating back to June 4, 1993.

Based on the reported survey data for MRT Non-Special volume, we found that 32 of the 68 (47%) facilities are currently not meeting the volume requirements they were originally approved under. In addition 2 of the 68 (2.9%) facilities do not have a radiation oncologist immediately available; 100% are in compliance with trained staff in CPR and other emergency interventions; 13.2% are not in compliance with having 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); 39.7% are not in compliance with having accreditation by the American College of Radiation/American Society for Radiation Oncology (ACR/ASTRO) or the American College of Radiation Oncology (ACRO); and 1.5% are not in compliance with having simulation capability at the same location.

The Department is in the process of confirming survey data/responses and collecting information on additional project delivery requirements, and sent out additional questionnaire. Please see table below for the breakdown of facilities under each standards:

Review Standards Effective Date	No. of Facilities Approved
June 4, 1993	1
April 28, 2000	9
January 30, 2006	9
November 13, 2008	11
November 21, 2011	12
May 24, 2013	17
September 14, 2015	9

# June 4, 1993 MRT Review Standards

Volume Requirements

Total	Met	Not Met	% Met	% Not Met
1	0	1	0%	100%

Have at least one radiation oncologist immediately available during the operation of the MRT unit(s).

Total	Met	Not Met	% Met	% Not Met
1	1	0	100%	0%

Have 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).

Total	Met	Not Met	% Met	% Not Met
1	1	0	100%	0%

Have accreditation by the American College of Radiology/American Society for Radiation Oncology (ACR/ASTRO) or the American College of Radiation Oncology (ACRO).

Total	Met	Not Met	% Met	% Not Met
1	0	1	0%	100%

# **April 28, 2000 MRT Review Standards**

Volume Requirements

Total	Met	Not Met	% Met	% Not Met
9	1	8	12%	88%

Have at least one radiation oncologist immediately available during the operation of the MRT unit(s).

Total	Met	Not Met	% Met	% Not Met
9	8	1	89%	11%

Have 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).

Total	Met	Not Met	% Met	% Not Met
9	7	2	78%	22%

Total	Met	Not Met	% Met	% Not Met
9	3	6	33%	67%

# January 30, 2006 MRT Review Standards

## Volume Requirements

Total	Met	Not Met	% Met	% Not Met
9	8	1	89%	11%

Have at least one radiation oncologist immediately available during the operation of the MRT unit(s).

Total	Met	Not Met	% Met	% Not Met
9	9	0	100%	0%

Have 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).

Total	Met	Not Met	% Met	% Not Met
9	9	0	100%	0%

Have accreditation by the American College of Radiology/American Society for Radiation Oncology (ACR/ASTRO) or the American College of Radiation Oncology (ACRO).

Total	Met	Not Met	% Met	% Not Met
9	7	2	78%	22%

# November 13, 2008 MRT Review Standards

## Volume Requirements

Total	Met	Not Met	% Met	% Not Met
11	9	2	82%	18%

Have at least one radiation oncologist immediately available during the operation of the MRT unit(s).

Total	Met	Not Met	% Met	% Not Met
11	11	0	100%	0%

Have 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).

Total	Met	Not Met	% Met	% Not Met
11	8	3	73%	27%

Total	Met	Not Met	% Met	% Not Met
11	7	4	64%	36%

# November 21, 2011 MRT Review Standards

# Volume Requirements

Total	Met	Not Met	% Met	% Not Met
12	4	8	34%	66%

Have at least one radiation oncologist immediately available during the operation of the MRT unit(s).

Total	Met	Not Met	% Met	% Not Met
12	12	0	100%	0%

Have 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).

Total	Met	Not Met	% Met	% Not Met
12	8	4	67%	33%

Have accreditation by the American College of Radiology/American Society for Radiation Oncology (ACR/ASTRO) or the American College of Radiation Oncology (ACRO).

Total	Met	Not Met	% Met	% Not Met
12	8	4	67%	33%

# May 24, 2013 MRT Review Standards

## Volume Requirements

Total	Met	Not Met	% Met	% Not Met
17	8	9	47%	53%

Have at least one radiation oncologist immediately available during the operation of the MRT unit(s).

Total	Met	Not Met	% Met	% Not Met
17	17	0	100%	0%

Have 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).

Total	Met	Not Met	% Met	% Not Met
17	16	1	94%	6%

Total	Met	Not Met	% Met	% Not Met
17	9	8	53%	47%

# September 14, 2015 MRT Review Standards

# Volume Requirements

Total	Met	Not Met	% Met	% Not Met
9	4	5	45%	55%

Have at least one radiation oncologist immediately available during the operation of the MRT unit(s).

Total	Met	Not Met	% Met	% Not Met
9	8	1	89%	11%

Have 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).

Total	Met	Not Met	% Met	% Not Met
9	9	0	100%	0%

Total	Met	Not Met	% Met	% Not Met
9	6	3	67%	33%

CON Projects for Psych Special Pool Beds - Report to CON Commission - March 2017								
Davida Dada	A -114							
Psych Beds	S - Adult							
CON No	LOI Recd Date	Facility No	Facility Name	Project Title	Facility City	Facility County	Existing Psych Beds? Y/N	Date Application Recd
400074	00/40/40	000004	Safehaus Geriatric	New Psych Hospital w/30 Psych SP Geriatric Beds	Detroit	MANANET		
160271	08/12/16	822001	Salenaus Genauic	New Psych Hospital w/20 Psych	Detroit	WAYNE	N	
160272	08/12/16	822001	Safehaus Safe Haven	SP Dev Disabled Adult Beds	Detroit	WAYNE	N	
160297	08/26/16	630120	McLaren Oakland	Add 20 Psych SP Geriatric Beds	Pontiac	Oakland	Y	02/01/2017
160296	08/26/16	740020	McLaren Port Huron	Add 7 Psych SP Geriatric Beds	Port Huron	St. Clair	Υ	
160304	09/01/16	090050	McLaren Bay Region	Add 20 Psych SP Geriatric Beds	Bay City	Bay	Υ	02/01/2017
16-0317	09/08/16	370010	McLaren Central Michigan	New Psych Unit with 6 Geriatric SP Psych Beds (**REQUESTING 8 BEDS IN APPLICATION**)	Mt. Pleasant	Isabella	N	02/01/2017
16-0326	09/13/16	820070	Garden City Hospital	New Psych Unit with 30 SP Med Psych Adult Beds	Garden City	WAYNE	N	02/01/2017
16-0329	09/14/16	580030	ProMedica Monroe Regional Hospital	Add 15 SP Med Psych Adult Beds	Monroe	Monroe	Y	02/01/2017
16-0345	10/07/16	412530	Pine Rest Christian Mental Health Services	Add 26 Psych SP Geriatric Beds	Grand Rapids	Kent	Y	02/01/2017
16-0369	11/01/16	290010	MidMichigan Medical Center - Gratiot	Add 4 Psych SP Geriatric Beds	Alma	Gratiot	Y	02/01/2017
16-0396	11/18/16	730060	Healthsource Saginaw	Add 16 Psych SP Geriatric Beds	Saginaw	Saginaw	Y	02/01/2017
16-0414	12/14/16	832633	BCA Stonecrest	Add 16 Psych SP Geriatric Beds	Detroit	WAYNE	Y	02/01/2017
16-0415	12/14/16	832633	BCA Stonecrest	Add 16 Psych SP Dev Disabled Adult Beds	Detroit	WAYNE	Υ	02/01/2017
17-0002	12/23/16	810030	St. Joseph Mercy Hospital	Add 8 Geriatric SP Psych Beds	Ann Arbor	Washtenaw	Y	
17-0021	01/16/2017	832628	SAMARITAN BEHAVIORAL CENTER	Add 30 Psych SP Geriatric Beds	Detroit	WAYNE	Y	02/01/2017
17-0057	02/16/2017	410080	SAINT MARY'S HEALTH CARE	Add 28 SP Med Psych Adult Beds	GRAND RAPIDS	KENT	Y	
			L				1	

Source: CON Evaluation Section, MDHHS CONGROUP/Project Coordinator

								achment I
	C	ON Projec	ts for Psych Special	Pool Beds - Report to Co	ON Commission	- March 2017		
<b>Psych Beds</b>	s - Child/A	Adolescen	<u>t</u>					
	LOI Recd						Existing Psych Beds?	Date
CON No	Date	Facility No.	Facility Name	Project Title	Facility City	Facility County	Y/N	Application Recd
160273	08/12/16	830450	Sinai-Grace Hospital	New Psych Unit with 10 Child Med Psych Beds		WAYNE	N	02/01/2017
160274	08/12/16		Sinai-Grace Hospital	New Psych Unit with 10 Child Dev Disabled Psych Beds			N	02/01/2017
16-0335	09/20/2016	502530	Harbor Oaks Hospital	Add 10 Psych SP Dev Disabled Child Beds	New Baltimore	Macomb	Υ	02/01/2017
16-0413	12/19/2016	832633	BCA Stonecrest	Add 5 Psych SP Dev Disabled Child Beds	DETROIT	WAYNE	Υ	
Summary								
Totals	Geriatirc	Dev Disability Adult	Dev Disability Child	Med Psych-Adult	Med Psych - Child			
Beds in CON Special Pool	110				20			
Beds requested in LOIs	183	36	25	73	10			
Beds requested in Applications [02/01/2017]	140	16	20	45	10			
Number of Applications [02/01/2017]	8	1	2	2	1			

Attachment J

## **CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN**

	2016 2017																							
Covered Service	J*	F	M*	Α	М	J*	J	Α	S*	0	N	D*	J*	F	M*	Α	М	J*	J	Α	S*	0	N	D*
Bone Marrow Transplantation (BMT) Services						• R	•	•	•	•	•	• R	•	•	• R-									
Cardiac Catheterization Services**										PC			• R A	•	S•	•		R			R			R <b>—</b>
Hospital Beds										PC			• R D	•	• R A									
Megavoltage Radiation Therapy (MRT) Services/Units										PC			• R A											
Nursing Home and Hospital Long-Term-Care Unit (NH- HLTCU) Beds	• R A	•	• A	•	•	•	•	•	•	•	•	•	•	•	• R-	•P	•	• <b>A</b> F						
Open Heart Surgery (OHS) Services										PC			• R A	•	•	•	•	• R <b>—</b>	•P	•	• <b>≜</b> F			
Positron Emission Tomography (PET) Scanner Services										PC			• R A											
Surgical Services										PC			• R A	•	•	•	•	• R <b>—</b>	•P	•	• <b>≜</b> F			
Urinary Extracorporeal Shock Wave Lithotripsy Services	• R A	•	•	•	•	•	•	•	•	•	•	• R <b>—</b>	•	•P	• <b>≜</b> F									
New Medical Technology Standing Committee	•M	∙M	•M	•M	∙M	•M	•M	∙M	•M	∙M	•M	∙M	•M	•M	•M	•M	•M	•M	•M	•M	∙M	•M	•M	•M
FY2017 CON Annual Report														_	_					•	•	•	•	• R <b>—</b>

#### KEY

- Receipt of proposed standards/documents, proposed Commission action
- Commission meeting
- Staff work/Standard advisory committee meetings
- ▲ Consider Public/Legislative comment
- \*\* Current in-process standard advisory committee or Informal Workgroup
- Staff work/Informal Workgroup/Commission Liaison Work/Standing Committee Work
- A Commission Action
- C Consider proposed action to delete service from list of covered clinical services requiring CON approve
- D Discussion
- F Final Commission action, Transmittal to Governor/Legislature for 45-day review period
- Monitor service or new technology for changes
- P Commission public hearing/Legislative comment period
- PC Public Comment Period for initial comments on review standards for review in the upcoming year
- R Receipt of report
- S Solicit nominations for standard advisory committee or standing committee membership

#### Approved January 26, 2017

The CON Commission may revise this work plan at each meeting. For information about the CON Commission work plan or how to be notified of CON Commission meetings, contact the Michigan Department of Health and Human Services (MDHHS), Office of Health Policy and Innovation, Planning and Access to Care Section, 15th Floor Grand Tower Bldg., 235 S. Grand Ave., Lansing, MI 48933, 517-335-6708, <a href="https://www.michigan.gov/con">www.michigan.gov/con</a>.

# SCHEDULE FOR UPDATING CERTIFICATE OF NEED (CON) STANDARDS EVERY THREE YEARS\*

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	June 2, 2014	2019
Bone Marrow Transplantation Services	September 29, 2014	2018
Cardiac Catheterization Services	September 14, 2015	2017
Computed Tomography (CT) Scanner Services	December 9, 2016	2019
Heart/Lung and Liver Transplantation Services	September 28, 2012	2018
Hospital Beds	March 20, 2015	2017
Magnetic Resonance Imaging (MRI) Services	October 21, 2016	2018
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	June 2, 2014	2017
Positron Emission Tomography (PET) Scanner Services	September 14, 2015	2020
Psychiatric Beds and Services	December 9, 2016	2018
Surgical Services	December 22, 2014	2017
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	December 22, 2014	2019

<sup>\*</sup>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."

<sup>\*\*</sup>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.