MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED (CON) COMMISSION MEETING

Thursday September 25, 2014

Capitol View Building
201 Townsend Street
MDCH Conference Center
Lansing, Michigan 48913

APPROVED MINUTES

I. Call to Order & Introductions

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

A. Members Present:

Kathleen Cowling, DO
James B. Falahee, Jr., JD
Marc Keshishian, MD, Chairperson
Denise Brooks-Williams
Charles Gayney
Robert Hughes
Jessica Kochin
Gay L. Landstrom, RN
Suresh Mukherji, MD, Vice-Chairperson
Luis Tomatis, MD

B. Members Absent

Gail J. Clarkson, RN

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Community Health Staff Present:

Scott Blakeney
Elizabeth Hertel
Natalie Kellogg
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Falahee, seconded by Commissioner Cowling, to approve the agenda as presented. Motion Carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of June 12, 2014

Motion by Commissioner Gayney, seconded by Commissioner Brooks-Williams, to approve the minutes of June 12, 2014 as presented. Motion Carried.

V. Computed Tomography (CT) Scanner Services, Magnetic Resonance Imaging (MRI) Services, Neonatal Intensive Care Unit (NICU) and Special Newborn Nursing Services, Surgical Services, and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services – July 23, 2014 Public Hearing Summary & Report

Ms. Rogers gave a background and overview of the public hearing summary and report on all of the above mentioned standards (see Attachment A).

A. Public comment

None.

B. Commission Discussion

No discussion.

C. Commission Final Action

Motion by Commissioner Falahee, seconded by Commissioner Landstrom, to approve and move the CT Scanner Services standards (see Attachment B) forward to the Joint Legislative Committee (JLC) and governor for the 45-day review period. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

Motion by Commissioner Falahee, seconded by Commissioner Kochin, to approve and move the MRI Services standards (see Attachment C) forward to the JLC and governor for the 45-day review period. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

Motion by Commissioner Landstrom, seconded by Commissioner Cowling, to approve and move the NICU and Special Newborn Nursing Services standards (see Attachment D) forward to the JLC and governor

for the 45-day review period. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

Motion by Commissioner Tomatis, seconded by Commissioner Cowling, to approve and move the Surgical Services standards (see Attachment E) forward to the JLC and governor for the 45-day review period. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

Motion by Commissioner Tomatis, seconded by Commissioner Cowling, to approve and move the UESWL Services standards (see Attachment F) forward to the JLC and governor for the 45-day review period. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

VI. Nursing Home and Hospital Long-Term Unit (NH-HLTCU) Beds – July 23, 2014 Public Hearing Summary & Report

Ms. Rogers gave background and overview of the public hearing summary and report (see Attachment G). The Department recommends approving the language as presented with the amendments but advises that the language will be subject to another public hearing.

Ms. Nagel provided an overview of the Department's response to the unresolved NH-HLTCU workgroup issues.

A. Public Comment

David Stobb, Ciena Healthcare
Pat Anderson, HCAM (see Attachment H)
Melissa Cupp, RWC Advocacy

B. Commission Discussion

Discussion followed.

C. Commission Final Action

Motion by Tomatis, to have the Department draft different language based on Dr. Keshishian's option 4, delegating the intent of the language to the Department. Motion Failed due to lack of a second.

Motion by Commissioner Falahee, seconded by Commissioner Cowling, to approve the language as presented with all amendments (see Attachment I), and send to public hearing and to the JLC. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

VII. Hospital Beds Draft Language & Effective Date of Updated Bed Need

Commissioner Brooks-Williams stated that she did not have a conflict of interest as the proposed language is applicable statewide. Mr. Potchen confirmed.

Ms. Rogers provided a background summary (see Attachment J).

Ms. Nagel gave a summary of the amended Hospital Bed language.

A. Public Comment

Karen Kippen, Henry Ford Health Systems (HFHS)

B. Commission Discussion

Discussion followed.

C. Commission Proposed Action

Motion by Commissioner Gayney, seconded by Commissioner Hughes, to accept the language as presented and move to public hearing and the JLC for review. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

Motion by Commissioner Falahee, seconded by Commissioner Cowling, to set the effective date for the new Bed Need numbers as November 1, 2014. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

VIII. Cardiac Catheterization (CC) Standard Advisory Committee (SAC) Update (Written Only)

Chairperson Keshishian advised Commission members that the written report was included in the electronic binder that was sent out prior to the meeting (see Attachment K).

IX. Megavoltage Radiation Therapy (MRT) Standard Advisory Committee (SAC) Update (Written Only)

Chairperson Keshishian advised Commission members that the written report was included in the electronic binder that was sent out prior to the meeting (see Attachment L).

X. Review Draft of CON Commission Biennial Report to JLC

Ms. Rogers gave a brief overview of the Biennial Report to the JLC (see Attachment M).

XI. Review MDCH Recommendations on Commission Bylaws Article VII(B)(3)(d) – SAC Provisions

Ms. Rogers gave the background and overview on the proposal removing VII(b)(3)(d) from the Bylaws, giving the Commission and Chairperson more flexibility (see Attachment N). The Commission will take final action on the Bylaws change at its December 11, 2014 meeting.

XII. Legislative Report

Ms. Hertel gave an overview of Michigan Senate Bill 1073.

XIII. Administrative Update

A. Planning and Access to Care

Ms. Nagel gave an update on the date of the Public Comment Period for the 2015 Review Standards.

B. CON Evaluation Section Update

1. Compliance Report (Written Report & Compliance Update see Attachment O)

Mr. Blakeney gave a summary of the compliance report.

2. Quarterly Performance Measures (Written Report see Attachment P)

Mr. Blakeney gave a summary of the quarterly performance report.

XIV. Legal Activity Report

Mr. Potchen gave an overview of the current legal activity report (see Attachment Q).

XV. Future Meeting Dates – December 11, 2014, January 28, 2015, March 18, 2015, June 11, 2015, September 24, 2015, and December 10, 2015

XVI. Public Comment

None.

XVII. Review of Commission Work Plan

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

C. Commission Discussion

None.

D. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner Tomatis, to accept the work plan as presented. Motion Carried in a vote of 10- Yes, 0- No, and 0- Abstained.

XVIII. Adjournment

Motion by Commissioner Gayney, seconded by Commissioner Cowling, to adjourn the meeting at 11:12 a.m. Motion Carried in a vote of 10- Yes, 0- No, and 0- Abstained.

Michigan Department of Community Health (MDCH or Department)
MEMORANDUM
Lansing, MI

Date: July 31, 2014

TO: CON Commission

FROM: MDCH

RE: Summary of Public Hearing Comments on Standards for: Nursing Home - Long Term Care Unit (NH-HLTCU) Beds, Computed Tomography (CT) Scanner Services, Magnetic Resonance Imaging (MRI) Services, Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services, Surgical Services, and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the NH-HLTCU Beds, CT Scanner Services, MRI Services, NICU and Special Newborn Nursing Services, Surgical Services, and UESWL Services/Units Standards at its June 12, 2014 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed Standards on July 23, 2014. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website.

NH-HLTCU Beds

Testimony was received from two organizations and is summarized as follows:

Karen Mesick, Pilgrim Manor

- Recommends removing the language added to access to care requirements specifically (lines 888 – 896):

  (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.

- States nursing facilities are not subject to the EMTALA laws as hospitals are, and additionally LTC providers do not have the benevolent are resources that hospitals have.

- LTC providers are required to ensure that they can provide for the residents care needs prior to admission. In order to determine if those clinical needs can be met, a provider should consider all payment options for that resident.

- States NH-HLTCU providers do have the rights under involuntary discharge criteria to discharge a patient for failure to pay, although very difficult to enforce, Federal law does provide recourse.

Patricia Anderson, Health Care Association of Michigan (HCAM)

- Recommends the revisions to the standards and states the changes will provide greater access to high quality care for those in need of NH-HLTCU services.

- The following language was proposed at the workgroup level: " at the Department's discretion, the Department may allow for the replacement of a previously approved new construction project that is yet to begin construction, from the original site to a proposed site within the planning area, if the applicant can demonstrate that utilizing the site originally approved for new construction will result in an undue hardship or insurmountable burden pursuant to this provision must be made in writing and supported by affidavit or other documentary evidence as required by the Department ."

- HCAM does not agree with the Department and supports the above language being incorporated into the standards, as the current CON practice of requiring a legal site description prior to receiving a CON approval is hindering investors and providers from moving forward with new constructions. The residents pay the price of not being served in the most modern facility that providers can build for them. HCAM would like the Commission to accept the language presented to the workgroup.

- Post-acute care providers have made continuous strides in providing more Medicare post-acute services from an average of less than 10% to over 20% of the days of care. This dynamic was discussed at the workgroup

meetings, but no appropriate change to the standards could be agreed upon. This post acute care provider focus will continue to grow and will be a concern that should be addressed in future reviews of these standards.

- HCAM does not support the language added to the access to care requirements, specifically, Section 11(3)(a)(i) and (iii). Nursing homes are not required to admit an individual if they cannot pay for the services. Nursing homes have a process established within their regulations "involuntary discharge patients for nonpayment."

- The standards have quality criteria that relates to the average number of citations at a D level or above from the annual LARA certification surveys. The most recent data is from March 2012 and the average is wrong. HCAM just wants to keep this issue on the front burners to either be corrected or eliminated from the standards.

CT Scanner Services

No testimony provided.

MRI Services

No testimony provided.

NICU and Special Newborn Nursing Services

No testimony provided.

Surgical Services

No testimony provided.

UESWL Services/Units

No testimony provided.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR COMPUTED TOMOGRAPHY (CT) SCANNER SERVICES

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

Section 1. Applicability

Sec. 1. These standards are requirements for the approval of the initiation, expansion, replacement, or acquisition of CT services and the delivery of services under Part 222 of the Code. Pursuant to Part 222 of the Code, CT is a covered clinical service. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

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

(a) "Acquisition of an existing CT scanner service" means obtaining possession or control of an existing fixed or mobile CT scanner service or existing CT scanner(s) by contract, ownership, or other comparable arrangement. For proposed projects involving mobile CT scanners, this applies to the central service coordinator and/or host facility.

(b) "Billable procedure" means a CT procedure billed as a single unit and performed in Michigan.

(c) "Body scans" include all spinal CT scans and any CT scan of an anatomical site below and including the neck.

(d) “Bundled body scan” means two or more body scans billed as one CT procedure.

(e) "Central service coordinator" means the organizational unit which has operational responsibility for a mobile CT scanner and which is a legal entity authorized to do business in the state of Michigan.

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

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

(h) "Computed tomography" or "CT" means the use of radiographic and computer techniques to produce cross-sectional images of the head or body.

(i) “CT-angio hybrid unit” means an integrated system comprised of both CT and angiography equipment sited in the same room that is designed specifically for interventional radiology or cardiac procedures. The CT unit is a guidance mechanism and is intended to be used as an adjunct to the procedure. The CT unit shall not be used for diagnostic studies unless the patient is currently undergoing a CT-angio hybrid procedure and is in need of a secondary diagnostic study.

(j) "CT equivalents" means the resulting number of units produced when the number of billable procedures for each category is multiplied by its respective conversion factor tabled in Section 22.

(k) "CT scanner" means x-ray CT scanning systems capable of performing CT scans of the head, other body parts, or full body patient procedures including Positron Emission Tomography (PET)/CT scanner hybrids if used for CT only procedures. The term does not include emission-computed tomographic systems utilizing internally administered single-photon gamma ray emitters, positron annihilation CT systems, magnetic resonance, ultrasound computed tomographic systems, CT simulators used solely for treatment planning purposes in conjunction with an MRT unit, and non-diagnostic, intra-operative guidance tomographic units.

(l) "CT scanner services" means the CON-approved utilization of a CT scanner(s) at one site in the case of a fixed CT scanner service or at each host site in the case of a mobile CT scanner service.

(m) “Dedicated pediatric CT” means a fixed CT scanner on which at least 70% of the CT procedures are performed on patients under 18 years of age.

(n) “Dental CT examinations” means use of a CT scanner specially designed to generate CT images to facilitate dental procedures.

(o) “Dental procedures” means dental implants, wisdom teeth surgical procedures, mandibular or maxillary surgical procedures, or temporal mandibular joint evaluations.

(p) "Department" means the Michigan Department of Community Health (MDCH).

(q) "Emergency room" means a designated area physically part of a licensed hospital and recognized by the Department as having met the staffing and equipment requirements for the treatment of emergency patients.

(r) “Excess CT Equivalents” means the number of CT equivalents performed by an existing CT scanner service in excess of 10,000 per fixed CT scanner and 4,500 per mobile CT scanner or either an existing fixed or mobile CT scanner service, the number of CT scanners used to compute excess CT equivalents shall include both existing and approved but not yet operational CT scanners. In the case of a CT scanner service that operates or has a valid CON to operate that has more than one fixed CT scanner at the same site, the term means number of CT equivalents in excess of 10,000 multiplied by the number of fixed CT scanners at the same site. For example, if a CT scanner service operates, or has a valid CON to operate, two fixed CT scanners at the same site, the excess CT equivalents is the number that is in excess of 20,000 (10,000 x 2) CT equivalents. In the case of an existing mobile CT scanner service, the term means the sum of all CT equivalents performed by the same mobile CT scanner service at all of the host sites combined that is in excess of 4,500. For example, if a mobile CT scanner service serves five host sites with 1 mobile CT scanner, the term means the sum of CT equivalents for all five host sites combined that is in excess of 4,500 CT equivalents.

(s) “Existing CT scanner service” means the utilization of a CON-approved and operational CT scanner(s) at one site in the case of a fixed CT scanner service or at each host site in the case of a mobile CT scanner service.

(t) “Existing CT scanner” means a CON-approved and operational CT scanner used to provide CT scanner services.

(u) “Existing mobile CT scanner service” means a CON-approved and operational CT scanner and transporting equipment operated by a central service coordinator serving two or more host sites.

(v) "Expand an existing CT scanner service" means the addition of one or more CT scanners at an existing CT scanner service.

(w) "Head scans" include head or brain CT scans; including the maxillofacial area; the orbit, sella, or posterior fossa; or the outer, middle, or inner ear; or any other CT scan occurring above the neck.

(x) "Health Service Area" or "HSA" means the groups of counties listed in Appendix A.

(y) “HIPAA” means the Health Insurance Portability and Accountability Act of 1996.

(z) “Hospital-based portable CT scanner or portable CT scanner” means a CT scanner capable of being transported into patient care areas (i.e., ICU rooms, operating rooms, etc.) to provide high-quality imaging of critically ill patients.

(aa) "Host site" means the site at which a mobile CT scanner is authorized to provide CT scanner services.

(bb) "Initiate a CT scanner service" means to begin operation of a CT scanner, whether fixed or mobile, at a site that does not perform CT scans as of the date an application is submitted to the Department. The term does not include the acquisition or replacement of an existing CT scanner service at the existing site or to a different site or the renewal of a lease.

(cc) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396w-5.

(dd) "Mobile CT scanner service" means a CT scanner and transporting equipment operated by a central service coordinator and which must serve two or more host facilities.

(ee) "Mobile CT scanner network" means the route (all host facilities) the mobile CT scanner is authorized to serve.

(ff) “Pediatric patient” means any patient less than 18 years of age.

(gg) "Replace an existing CT scanner" means an equipment change of an existing CT scanner, that requires a change in the radiation safety certificate, proposed by an applicant which results in that

applicant operating the same number of CT scanners before and after project completion, at the same geographic location. The term also includes relocating an existing CT scanner or CT scanner service from an existing site to a different site.

(hh) "Sedated patient" means a patient that meets all of the following:

(i) Patient undergoes procedural sedation and whose level of consciousness is either moderate sedation or a higher level of sedation, as defined by the American Association of Anesthesiologists, the American Academy of Pediatrics, the Joint Commission on the Accreditation of Health Care Organizations, or an equivalent definition.

(ii) Who requires observation by personnel, other than technical employees routinely assigned to the CT unit, who are trained in cardiopulmonary resuscitation (CPR) and pediatric advanced life support (PALS).

(ii) "Special needs patient" means a non-sedated patient, either pediatric or adult, with any of the following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD), developmental delay, malformation syndromes, hunter's syndrome, multi-system disorders, psychiatric disorders, and other conditions that make the patient unable to comply with the positional requirements of the exam.

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

Section 3. Requirements for approval for applicants proposing to initiate a CT scanner service

Sec. 3. An applicant proposing to initiate a CT scanner service, other than a dental CT scanner service or a hospital-based portable CT scanner service, shall demonstrate the following, as applicable:

(1) A hospital proposing to initiate its first fixed CT scanner service shall demonstrate each of the following:

(a) The proposed site is a hospital licensed under Part 215 of the Code.

(b) The hospital operates an emergency room that provides 24-hour emergency care services as authorized by the local medical control authority to receive ambulance runs.

(2) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1), proposing to initiate a fixed CT scanner service shall project an operating level of at least 7,500 CT equivalents per year for the second 12-month period after beginning operation of the CT scanner.

(3) An applicant proposing to initiate a mobile CT scanner service shall project an operating level of at least 3,500 CT equivalents per year for the second 12-month period after beginning operation of the CT scanner.

(4) An applicant proposing to initiate CT scanner services as an existing host site on a different mobile CT scanner service shall demonstrate the following:

(a) The applicant provides a proposed route schedule.

(b) The applicant provides a draft contract for services between the proposed host site and central service coordinator.

Section 4. Requirements for approval for applicants proposing to initiate a dental CT scanner service

Sec. 4. An applicant proposing to initiate a fixed or mobile dental CT scanner service shall demonstrate each of the following, as applicable:

(1) An applicant is proposing a dental CT scanner service for the sole purpose of performing dental CT examinations.

(2) The CT scanner generates a peak power of 5 kilowatts or less as certified by the manufacturer.

(3) An applicant proposing to initiate a dental CT scanner service, other than an applicant that is proposing a dental CT scanner service in HSA 8, shall project an operating level of at least 200 dental CT examinations per year for the second 12-month period after beginning operation of the dental CT scanner.

(4) The applicant has demonstrated to the satisfaction of the Department that the person(s) (e.g., technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.

(5) The applicant has demonstrated to the satisfaction of the Department that the dental CT examinations generated by the proposed dental CT scanner will be interpreted by a licensed dentist(s) trained and/or certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.

(6) An applicant proposing to initiate mobile dental CT scanner services as an existing host site on a different mobile dental CT scanner service shall demonstrate the following:
(a) The applicant provides a proposed route schedule.
(b) The applicant provides a draft contract for services between the proposed host site and central service coordinator.

Section 5. Requirements for approval for applicants proposing to expand an existing CT scanner service

Sec. 5. An applicant proposing to expand an existing CT scanner service, other than a dental CT scanner service or a hospital-based portable CT scanner service, shall demonstrate the following, as applicable:

(1) An applicant proposing to expand an existing fixed CT scanner service shall demonstrate that all of the applicant's fixed CT scanners, excluding CT scanners approved pursuant to sections 6, 13, 14, and 18, have performed an average of at least 10,000 CT equivalents per fixed CT scanner for the most recent continuous 12-month period preceding the applicant's request. In computing this average, the Department will divide the total number of CT equivalents performed by the applicant's total number of fixed CT scanners, including both operational and approved but not operational fixed CT scanners.

(2) An applicant proposing to expand an existing fixed CT scanner service approved pursuant to Section 18 shall demonstrate that all of the applicant’s dedicated pediatric CT scanners have performed an average of at least 3,000 CT equivalents per dedicated pediatric CT scanner for the most recent continuous 12-month period preceding the applicant’s request. In computing this average, the Department will divide the total number of CT equivalents performed by the applicant’s total number of dedicated pediatric CT scanners, including both operational and approved but not operational dedicated pediatric CT scanners.

(3) If an applicant proposes to expand an existing mobile CT scanner service, the applicant shall demonstrate that all of the applicant's mobile CT scanners have performed an average of at least 5,500 CT equivalents per mobile CT scanner for the most recent continuous 12-month period preceding the applicant's request. In computing this average, the Department will divide the total number of CT equivalents performed by the applicant's total number of mobile CT scanners, including both operational and approved but not operational mobile CT scanners.

Section 6. Requirements for approval for applicants proposing to expand an existing dental CT scanner service

Sec. 6. An applicant proposing to expand an existing fixed or mobile dental CT scanner service shall demonstrate that all of the applicant's dental CT scanners have performed an average of at least 300 dental CT examinations per fixed or mobile dental CT scanner for the most recent continuous 12-month period preceding the applicant's request. In computing this average, the Department will divide the total number of dental CT examinations performed by the applicant's total number of fixed or mobile dental CT scanners, including both operational and approved but not operational fixed or mobile dental CT scanners.

Section 7. Requirements for approval for applicants proposing to replace an existing CT scanner

Sec. 7. An applicant proposing to replace an existing CT scanner or service, other than a dental CT scanner service or a hospital-based portable CT scanner service, shall demonstrate the following, as applicable:

(1) An applicant proposing to replace an existing fixed, mobile, or dedicated pediatric CT scanner shall demonstrate all of the following:

(a) The replacement CT scanner will be located at the same site as the CT scanner to be replaced.

(b) The existing CT scanner(s) proposed to be replaced is fully depreciated according to generally accepted accounting principles, or, that the existing equipment clearly poses a threat to the safety of the public, or, that the proposed replacement CT scanner offers technological improvements which enhance quality of care, increase efficiency, and/or reduce operating costs and patient charges.

(2) An applicant proposing to replace an existing fixed CT scanner service to a different site shall demonstrate that the proposed project meets all of the following:

(a) The existing fixed CT scanner service to be replaced has been in operation for at least 36 months as of the date an application is submitted to the Department.

(b) The proposed new site is within a 10-mile radius of a site at which an existing fixed CT scanner service is located if an existing fixed CT scanner service is located in a metropolitan statistical area county, or a 20-mile radius if an existing fixed CT scanner service is located in a rural or micropolitan statistical area county.

(c) The CT scanner service to be replaced performed at least an average of 7,500 CT equivalents per fixed scanner in the most recent 12-month period for which the Department has verifiable data, except for an applicant that meets all of the requirements of Section 3(1).

(d) The applicant agrees to operate the CT scanner service in accordance with all applicable project delivery requirements set forth in Section 20 of these standards.

(3) An applicant proposing to replace a fixed CT scanner(s) of an existing CT scanner service to a different site shall demonstrate that the proposed project meets all of the following:

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

(b) The proposed new site is within a 10-mile radius of a site at which an existing fixed CT scanner service is located if an existing fixed CT scanner service is located in a metropolitan statistical area county, or a 20-mile radius if an existing fixed CT scanner service is located in a rural or micropolitan statistical area county..

(c) Each existing CT scanner at the service from which a scanner is to be replaced performed at least an average of 7,500 CT equivalents per fixed scanner in the most recent 12-month period for which the Department has verifiable data.

(d) The applicant agrees to operate the CT scanner(s) at the proposed site in accordance with all applicable project delivery requirements set forth in Section 20 of these standards.

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

Section 8. Requirements for approval for applicants proposing to replace an existing dental CT scanner

Sec. 8. An applicant proposing to replace an existing dental CT scanner or service shall demonstrate the following, as applicable:

(1) An applicant proposing to replace an existing fixed or mobile dental CT scanner shall demonstrate all of the following:

(a) The replacement dental CT scanner will be located at the same site as the dental CT scanner to be replaced.

(b) the existing dental CT scanner(s) proposed to be replaced is fully depreciated according to generally accepted accounting principles, or, that the existing equipment clearly poses a threat to the safety of the public, or that the proposed replacement dental CT scanner offers technological improvements which enhance quality of care, increase efficiency, and/or reduce operating costs and patient charges.

(2) An applicant proposing to replace an existing fixed dental CT scanner service to a different site shall demonstrate that the proposed project meets all of the following:

(a) The existing fixed dental CT scanner service to be replaced has been in operation for at least 36 month as of the date an application is submitted to the Department.

(b) The proposed new site is within a 10-mile radius of a site at which an existing fixed dental CT scanner service is located if an existing fixed dental CT scanner service is located in a metropolitan statistical area county, or a 20-mile radius if an existing fixed dental CT scanner service is located in a rural or micropolitan statistical area county.

(c) The dental CT scanner service to be replaced performed at least an average of 200 dental CT examinations per fixed dental CT scanner in the most recent 12-month period for which the Department has verifiable data.

(d) The applicant agrees to operate the dental CT scanner service in accordance with all applicable project delivery requirements set forth in Section 20 of these standards.

(3) An applicant proposing to replace a fixed dental CT scanner(s) of an existing dental CT scanner service to a different site shall demonstrate that the proposed project meets all of the following:

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

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

(c) The proposed new site is within a 10-mile radius of a site at which an existing fixed dental CT scanner service is located if an existing fixed dental CT scanner service is located in a metropolitan statistical area county, or a 20-mile radius if an existing fixed dental CT scanner service is located in a rural or micropolitan statistical area county.

(d) Each existing dental CT scanner at the service from which a scanner is to be replaced performed at least an average of 200 dental CT examinations per fixed dental CT scanner in the most recent 12-month period for which the Department has verifiable data.

(e) The applicant agrees to operate the dental CT scanner(s) at the proposed site in accordance with all applicable project delivery requirements set forth in Section 20 of these standards.

Section 9. Requirements for approval for applicants proposing to acquire an existing CT scanner service or an existing CT scanner(s)

Sec. 9. An applicant proposing to acquire an existing fixed or mobile CT scanner service, other than a dental CT scanner service or a hospital-based portable CT scanner service, shall demonstrate the following, as applicable:

(1) An applicant proposing to acquire an existing fixed or mobile CT scanner service, shall demonstrate that a proposed project meets all of the following:

(a) For an application for the proposed first acquisition of an existing fixed or mobile CT scanner service, for which a final decision has not been issued after June 4, 2004, an existing CT scanner service to be acquired shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs. The CT scanner service shall be operating at the applicable volume requirements set forth in Section 20 of these standards in the second 12 months after the date the service is acquired, and annually thereafter.

(b) For any application for proposed acquisition of an existing fixed or mobile CT scanner service, an applicant shall be required to demonstrate the following, as applicable:

(i) The fixed CT scanner service to be acquired performed at least 7,500 CT equivalents per fixed CT scanner in the most recent 12-month period for which the Department has verifiable data, unless an applicant meets all of the requirements of Section 3(1).

(ii) The mobile CT scanner service to be acquired performed at least 3,500 CT equivalents per mobile CT scanner in the most recent 12-month period for which the Department has verifiable data.

(2) An applicant proposing to acquire an existing fixed or mobile CT scanner(s) of an existing fixed or mobile CT scanner service shall demonstrate that the proposed project meets the following:

(a) For any application for proposed acquisition of an existing fixed or mobile CT scanner(s) of an existing fixed or mobile CT scanner service, an applicant shall be required to demonstrate the following, as applicable:

(i) The fixed CT scanner(s) to be acquired performed at least 7,500 CT equivalents per fixed CT scanner in the most recent 12-month period for which the department has verifiable data.

(ii) The mobile CT scanner(s) to be acquired performed at least 3,500 CT equivalents per mobile CT scanner in the most recent 12-month period for which the Department has verifiable data.

Section 10. Requirements for approval for applicants proposing to acquire an existing dental CT scanner service or an existing dental CT scanner(s)

Sec. 10. (1) An applicant proposing to acquire an existing fixed or mobile dental CT scanner service shall demonstrate that a proposed project meets all of the following:

(a) For an application for the proposed first acquisition of an existing fixed or mobile dental CT scanner service, for which a final decision has not been issued after the effective date of these standards, an existing dental CT scanner service to be acquired shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs. The dental CT scanner service shall be operating at the applicable volume requirements set forth in Section 20 of these standards in the second 12 months after the date the service is acquired, and annually thereafter.

(b) For any application for proposed acquisition of an existing fixed or mobile dental CT scanner service, an applicant shall be required to demonstrate that the CT scanner service to be acquired performed at least 200 dental CT examinations per dental CT scanner in the most recent 12-month period, for which the Department has verifiable data.

(2) An applicant proposing to acquire an existing fixed dental CT scanner(s) of an existing fixed or mobile dental CT scanner service shall demonstrate that the proposed project meets the following:

(a) For any application for proposed acquisition of an existing fixed or mobile dental CT scanner(s) of an existing fixed or mobile dental CT scanner service, an applicant shall be required to demonstrate that the fixed or mobile dental CT scanner(s) to be acquired performed at least 200 dental CT examinations per dental CT scanner in the most recent 12-month period for which the Department has verifiable data.

Section 11. Requirements for a dedicated research fixed CT scanner

Sec. 11. An applicant proposing to add a fixed CT scanner to an existing CT scanner service for exclusive research use shall demonstrate the following:

(1) The applicant agrees that the dedicated research CT scanner will be used primarily (70% or more of the scans) for research purposes.

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

(3) The proposed site can have no more than three dedicated research fixed CT scanners approved under this section.

(4) The dedicated research scanner approved under this section may not utilize CT procedures performed on the dedicated CT scanner to demonstrate need or to satisfy CT CON review standards requirements.

Section 12. Requirements for approval of an applicant proposing a CT scanner used for the sole purpose of performing dental CT examinations exclusively for research

Sec. 12. (1) An applicant proposing a CT scanner used for the sole purpose of performing dental CT examinations exclusively for research shall demonstrate each of the following:

(a) The applicant operates a dental radiology program in a certified dental school.

(b) The research dental CT scanner shall operate under a protocol approved by the applicant's institutional review board.

(c) The applicant agrees to operate the research dental CT scanner in accordance with the terms of approval in Section 20(6).

(2) An applicant meeting the requirements of subsection (1) shall also demonstrate compliance with the requirements of sections 4(2), 4(4) and 4(5).

Section 13. Requirements for approval of a hospital-based portable CT scanner for initiation, expansion, replacement, and acquisition

Sec. 13. An applicant proposing to initiate, expand, replace, or acquire a hospital-based portable CT scanner shall demonstrate that it meets all of the following:

(1) An applicant is limited to the initiation, expansion, replacement, or acquisition of no more than two hospital-based portable CT scanners.

(2) The proposed site is a hospital licensed under Part 215 of the Code.

(3) The hospital has been certified as a level I or level II trauma facility by the American College of Surgeons, or has performed >100 craniotomies in the most recent 12- month period verifiable by the Department.

(4) The applicant agrees to operate the hospital-based portable CT scanner in accordance with all applicable project delivery requirements set forth in Section 20 of these standards.

(5) The approved hospital-based portable CT scanner will not be subject to CT volume requirements.

(6) The applicant may not utilize CT procedures performed on a hospital-based portable CT scanner to demonstrate need or to satisfy CT CON review standards requirements.

Section 14. Requirements for approval of a PET/CT hybrid for initiation, expansion, replacement, and acquisition

Sec. 14. An applicant proposing to initiate, expand, replace, or acquire a PET/CT hybrid shall demonstrate that it meets all of the following:

(1) There is an approved PET CON for the PET/CT hybrid, and the PET/CT hybrid is in compliance with all applicable project delivery requirements as set forth in the CON review standards for PET.

(2) The applicant agrees to operate the PET/CT hybrid in accordance with all applicable project delivery requirements set forth in Section 20 of these standards.

(3) The approved PET/CT hybrid will not be subject to CT volume requirements.

(4) A PET/CT scanner hybrid approved under the CON Review Standards for PET Scanner Services and the Review Standards for CT Scanner Services may not utilize CT procedures performed on a hybrid scanner to demonstrate need or to satisfy CT CON review standards requirements.

Section 15. Requirements for approval of a CT-angio hybrid unit for initiation, replacement, and acquisition

Sec. 15. An applicant proposing to initiate, replace, or acquire a hospital-based CT-angio hybrid unit shall demonstrate each of the following, as applicable to the proposed project:

(1) The proposed site is a licensed hospital under Part 215 of the Code.

(2) The proposed site has an existing fixed CT scanner service that has been operational for the previous 36 consecutive months and is meeting its minimum volume requirements.

(3) The proposed site offers the following services:
(a) diagnostic cardiac catheterization; or
(b) interventional radiology; or
(c) surgical services

(4) The proposed CT-angio hybrid unit must be located in one of the following rooms:
(a) cardiac catheterization lab; or
(b) interventional radiology suite; or
(c) licensed operating room

(5) Diagnostic CT studies shall not be performed on a CT-angio hybrid unit approved under this section unless the patient is currently undergoing a CT-angio hybrid interventional procedure and is in need of a secondary diagnostic CT study.

(6) The approved CT-angio hybrid shall not be subject to CT volume requirements.

(7) The applicant shall not utilize the procedures performed on the CT-angio hybrid unit to demonstrate need or to satisfy CT CON review standards requirements.

Section 16. Additional requirements for approval of a mobile CT scanner service

Sec. 16. (1) An applicant proposing to initiate a mobile CT scanner service in Michigan shall demonstrate that it meets all of the following additional requirements:

(a) A separate CON application shall be submitted by the central service coordinator and each Michigan host facility.

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

(2) An applicant proposing to become a host facility on an existing mobile CT scanner network shall demonstrate that it meets all of the following additional requirements:

(a) Approval of the application will not result in an increase in the number of operating mobile CT scanners for the mobile CT scanner network unless the requirements of Section 5 have been met.

(b) A separate CON application has been filed for each host facility.

Section 17. Additional requirements for approval of a mobile dental CT scanner service

Sec. 17. (1) An applicant proposing to initiate a mobile dental CT scanner service in Michigan shall demonstrate that it meets all of the following additional requirements:

(a) A separate CON application shall be submitted by the central service coordinator and each Michigan host facility.

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

(2) An applicant proposing to become a host facility on an existing mobile dental CT scanner network shall demonstrate that it meets all of the following additional requirements:

(a) Approval of the application will not result in an increase in the number of operating mobile dental CT scanners for the mobile dental CT scanner network unless the requirements of Section 6 have been met.

(b) A separate CON application has been filed for each host facility.

Section 18. Requirements for approval of an applicant proposing to establish dedicated pediatric CT Scanner

Sec. 18. (1) An applicant proposing to establish dedicated pediatric CT shall demonstrate all of the following:

(a) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges (excluding normal newborns) in the most recent year of operation.

(b) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the most recent year of operation.

(c) The applicant shall have an active medical staff, at the time the application is submitted to the Department that includes, but is not limited to, physicians who are fellowship-trained in the following pediatric specialties:

(i) pediatric radiology (at least two)
(ii) pediatric anesthesiology
(iii) pediatric cardiology
(iv) pediatric critical care
(v) pediatric gastroenterology
(vi) pediatric hematology/oncology
(vii) pediatric neurology
(viii) pediatric neurosurgery
(ix) pediatric orthopedic surgery
(x) pediatric pathology
(xi) pediatric pulmonology
(xii) pediatric surgery

(xiii) neonatology

(d) The applicant shall have in operation the following pediatric specialty programs at the time the application is submitted to the Department:

(i) pediatric bone marrow transplant program

(ii) established pediatric sedation program

(iii) pediatric open heart program

(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements of Section 3 of these standards.

Section 19. Requirements for Medicaid participation

Sec. 19. An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

Section 20. Project delivery requirements and terms of approval for all applicants

Sec. 20. An applicant shall agree that, if approved, the CT scanner(s) services shall be delivered in compliance with the following terms of approval.

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) The applicant shall establish a mechanism to assure that the CT scanner facility is staffed so that:

(i) The screening of requests for CT procedures and interpretation of CT procedures will be performed by physicians with training and experience in the appropriate diagnostic use and interpretation of cross-sectional images of the anatomical region(s) to be examined, and

(ii) The CT scanner is operated by physicians and/or is operated by radiological technologists qualified by training and experience to operate the CT scanner safely and effectively.

For purposes of evaluating (a)(i), the Department shall consider it prima facie evidence of a satisfactory assurance mechanism as to screening and interpretation if the applicant requires the screening of requests for and interpretations of CT procedures to be performed by physicians who are board certified or eligible in radiology or are neurologists or other specialists trained in cross-sectional imaging of a specific organ system. For purposes of evaluating (a)(i) the Department shall consider it prima facie evidence of a satisfactory assurance mechanism as to the operation of a CT scanner if the applicant requires the CT scanner to be operated by a physician or by a technologist registered by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT). However, the applicant may submit and the Department may accept other evidence that the applicant has established a mechanism to assure that the CT scanner facility is appropriately and adequately staffed as to screening, interpretation, and/or operation of a CT scanner.

(b) The applicant shall employ or contract with a radiation physicist to review the quality and safety of the operation of the CT scanner.

(c) The applicant shall assure that at least one of the physicians responsible for the screening and interpretation as defined in subsection (a)(i) will be in the CT facility or available on a 24-hour basis (either on-site or through telecommunication capabilities) to make the final interpretation.

(d) In the case of an urgent or emergency CT scan, the applicant shall assure that a physician so authorized by the applicant to interpret initial scans will be on-site or available through telecommunication capabilities within 1 hour following completion of the scanning procedure to render an initial interpretation of the scan. A final interpretation shall be rendered by a physician so authorized under subsection (a)(i) within 24 hours.

(e) The applicant shall have, within the CT scanner facility, equipment and supplies to handle clinical emergencies that might occur within the CT unit, with CT facility staff trained in CPR and other appropriate

emergency interventions, and a physician on site in or immediately available to the CT scanner at all times when patients are undergoing scans.

(f) Fixed CT scanner services at each facility shall be made available 24 hours a day for emergency patients.

(g) The applicant shall accept referrals for CT scanner services from all appropriately licensed practitioners.

(h) The applicant shall establish and maintain: (a) a standing medical staff and governing body (or its equivalent) requirement that provides for the medical and administrative control of the ordering and utilization of CT patient procedures, and (b) a formal program of utilization review and quality assurance. These responsibilities may be assigned to an existing body of the applicant, as appropriate.

(i) An applicant approved under Section 18 must be able to prove that all radiologists, technologists and nursing staff working with CT patients have continuing education or in-service training on pediatric low-dose CT. The site must also be able to provide evidence of defined low-dose pediatric CT protocols.

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

(a) The applicant, to assure that the CT scanner will be utilized by all segments of the Michigan population, shall:

(i) not deny any CT scanner services to any individual based on ability to pay or source of payment;

(ii) provide all CT scanning services to any individual based on the clinical indications of need for the service; and

(iii) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

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

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

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

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

(a) The approved CT scanners shall be operating at an average of 7,500 CT equivalents scanner per fixed scanner and 3,500 CT equivalents per mobile scanner per year for the second 12-month period after beginning operation of the CT scanner, and annually thereafter, except for those scanners exempt under applicable sections.

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

(c) Equipment to be replaced shall be removed from service.

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

(e) An applicant approved under Section 4 shall not be required to be in compliance with subsection (2).

(5) Compliance with the following dental CT scanner (fixed or mobile) requirements, if applicable:

(a) The CT scanner will be used for the sole purpose of dental CT examinations.

(b) The applicant shall demonstrate to the satisfaction of the Department that the person(s) (e.g., technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental

school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.

(c) The applicant shall demonstrate to the satisfaction of the Department that the dental CT examinations generated by the dental CT scanner will be interpreted by a licensed dentist(s) trained and/or certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.

(d) The applicant shall demonstrate to the satisfaction of the Department that the dentists using the dental CT examinations for performing dental procedures has had the appropriate training and/or experience certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.

(e) The applicant, to assure that the dental CT scanner will be utilized by all segments of the Michigan population, shall:

(i) not deny dental CT scanner services to any individual based on ability to pay or source of payment;

(ii) provide dental CT scanning services to any individual based on the clinical indications of need for the service; and

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

(f) The CT scanner shall be operating at least 200 CT equivalents per year for the second 12-month period after beginning operation of the dental CT scanner and annually thereafter.

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

(h) Equipment to be replaced shall be removed from service.

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

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

(6) An applicant for a CT scanner used for dental research under Section 12(1) shall agree that the services provided by the CT scanner approved pursuant to Section 12(1) shall be delivered in compliance with the following terms of CON approval:

(a) The capital and operating costs relating to the CT scanner used for dental research pursuant to Section 12(1) shall be charged only to a specific research account(s) and not to any patient or third-party payor.

(b) The CT scanner used for dental research approved pursuant to Section 12(1) shall not be used for any purposes other than as approved by the institutional review board unless the applicant has obtained CON approval for the CT scanner pursuant to part 222 and these standards, other than Section 12.

(7) An applicant approved under Section 13 shall be in compliance with the following:

(a) Portable CT scanner can only be used by a qualifying program for the following purposes:

(i) Brain scanning of patients being treated in an adult or pediatric Intensive Care Unit (ICU).

(ii) Non-diagnostic, intraoperative guidance in an operating room.

(b) The approved applicant must provide annual reports to the Department by January 31st of each year for the preceding calendar year. This requirement applies to all applicants approved under Section 13.

(c) The following data must be reported to the Department:

(i) Number of adult studies (age>=18)

(ii) Number of pediatric studies (age<18)

(iii) Number of studies performed using a portable CT on the same patient while that patient is in an ICU

(8) An applicant approved under Section 15 shall be in compliance with the following:

(a) The proposed site offers the following services:

(i) diagnostic cardiac catheterization; or

(ii) interventional radiology; or

(iii) surgical services

(b) The proposed CT-Angio hybrid unit must be located in one of the following rooms:

(i) cardiac catheterization lab; or

(ii) interventional radiology suite; or

(iii) licensed operating room

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

Section 21. Project delivery requirements and additional terms of approval for applicants involving mobile CT scanners

Sec. 21. (1) In addition to the provisions of Section 20, an applicant for a mobile CT scanner shall agree that the services provided by the mobile CT scanner(s) shall be delivered in compliance with the following terms of CON approval:

(a) A host facility shall submit only one CON application for a CT scanner for review at any given time.

(b) A mobile CT scanner with an approved CON shall notify the Michigan Department of Community Health prior to ending service with an existing host facility.

(c) A CON shall be required to add a host facility.

(d) A CON shall be required to change the central service coordinator.

(e) Each host facility must have at least one board certified or board eligible radiologist on its medical staff. The radiologist(s) shall be responsible for: (i) establishing patient examination and infusion protocol, and (ii) providing for the interpretation of scans performed by the mobile CT scanner.

(f) Each mobile CT scanner service must have an Operations Committee with members representing each host facility, the central service coordinator, and the central service medical director. This committee shall oversee the effective and efficient use of the CT scanner, establish the normal route schedule, identify the process by which changes are to be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile CT scanner on at least a quarterly basis.

(g) The central service coordinator shall arrange for emergency repair services to be available 24 hours each day for the mobile CT scanner as well as the vehicle transporting the equipment. In addition, to preserve image quality and minimize CT scanner downtime, calibration checks shall be performed on the CT scanner at least once each work day and routine maintenance services shall be provided on a regularly scheduled basis, at least once a week during hours not normally used for patient procedures.

(h) Each host facility must provide a properly prepared parking pad for the mobile CT scanner of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host facility must also provide the capability for processing the film and maintaining the confidentiality of patient

records. A communication system must be provided between the mobile vehicle and each host facility to provide for immediate notification of emergency medical situations.

(i) A mobile CT scanner service shall operate under a contractual agreement that includes the provision of CT scanner services at each host facility on a regularly scheduled basis.

(j) The volume of utilization at each host facility shall be reported to the Department by the central service coordinator under the terms of Section 20(2)(i).

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

Section 22. Determination of CT Equivalents

Sec. 22. CT equivalents shall be calculated as follows:

(a) Each billable procedure for the time period specified in the applicable section(s) of these standards shall be assigned to a category set forth in Table 1.

(b) The number of billable procedures for each category in the time period specified in the applicable section(s) of these standards shall be multiplied by the corresponding conversion factor in Table 1 to determine the number of CT equivalents for that category for that time period.

(c) The number of CT equivalents for each category shall be summed to determine the total CT equivalents for the time period specified in the applicable section(s) of these standards.

(d) The conversion factor for pediatric/special needs patients does not apply to procedures performed on a dedicated pediatric CT scanner.

Table 1 Category	Number of Billable CT Procedures		Conversion Factor		CT Equivalents
<u>Adult Patient</u>					
Head Scans w/o Contrast	_____	X	1.00	=	_____
(includes dental CT examinations)					
Head Scans with Contrast	_____	X	1.25	=	_____
Head Scans w/o & w Contrast	_____	X	1.75	=	_____
Body Scans w/o Contrast	_____	X	1.50	=	_____
Body Scans with Contrast	_____	X	1.75	=	_____
Body Scans w/o & w Contrast	_____	X	2.75	=	_____
Bundled body Scan	_____	X	3.50	=	_____
<u>Pediatric/Special Needs Patient</u>					
Head scans w/o Contrast	_____	x	1.25	=	_____
(includes dental CT examinations)					
Head Scans with Contrast	_____	x	1.50	=	_____
Head Scans w/o & with Contrast	_____	x	2.00	=	_____
Body Scans w/o Contrast	_____	x	1.75	=	_____
Body Scans with Contrast	_____	x	2.00	=	_____
Body Scans w/o & with Contrast	_____	x	3.00	=	_____
Bundled body Scan	_____	X	4.00	=	_____
Total CT Equivalents					_____

Section 23. Documentation of projections

Sec. 23. An applicant required to project volumes under sections 3 and 4 shall demonstrate the following, as applicable:

(1) An applicant required to project under Section 3 shall demonstrate that the projection is based on historical physician referrals that resulted in an actual scan for the most recent 12-month period immediately preceding the date of the application. Historical physician referrals will be verified with the data maintained by the Department through its "Annual Hospital statistical survey" and/or "Annual Freestanding Statistical Survey."

(2) An applicant required to project under Section 4 shall demonstrate that the projection is based on a combination of the following for the most recent 12-month period immediately preceding the date of the application:

(a) the number of dental procedures performed by the applicant, and

(b) the number of committed dental procedures performed by referring licensed dentists. Further, the applicant and the referring licensed dentists shall substantiate the numbers through the submission of HIPAA compliant billing records.

(3) An applicant shall demonstrate that the projected number of referrals to be performed at the proposed site under subsection (1) are from an existing CT scanner service that is in compliance with the volume requirements applicable to that service, and will continue to be in compliance with the volume requirements applicable to that service subsequent to the initiation of the proposed CT scanner service by an applicant. This does not include dental CT scanners. Only excess CT equivalents equal to or greater than what is being committed pursuant to this subsection may be used to document projections under subsection (1). In demonstrating compliance with this subsection, an applicant shall provide each of the following:

(a) A written commitment from each referring physician that he or she will refer at least the volume of CT scans to be transferred to the proposed CT scanner service for no less than 3 years subsequent to the initiation of the CT scanner service proposed by an applicant.

(b) The number of referrals committed must have resulted in an actual CT scan of the patient at the existing CT scanner service from which referral will be transferred. The committing physician must make available HIPAA compliant audit material if needed upon Department request to verify referral sources and outcomes. Commitments must be verified by the most recent data set maintained by the Department through its "Annual Hospital Statistical Survey" and/or "Annual Freestanding Statistical Survey."

(c) The projected referrals are from an existing CT scanner service within a 75-mile radius for rural and micropolitan statistical area counties or 20-mile radius for metropolitan statistical area counties.

Section 24. Effect on prior CON review standards; comparative reviews

Sec. 24. (1) These CON review standards supersede and replace the CON Review Standards for Computed Tomography Scanner Services approved by the CON Commission on ~~December 15, 2011~~MARCH 18, 2014 and effective on ~~February 27, 2012~~JUNE 2, 2014.

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

APPENDIX A

Counties assigned to each of the health service areas are as follows:

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

APPENDIX B

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

Allegan	HILLSDALE	MASON
Alpena	Houghton	Mecosta
Benzie	IONIA	Menominee
Branch	Isabella	~~Midland~~
Chippewa	Kalkaska	Missaukee
Delta	Keweenaw	St. Joseph
Dickinson	Leelanau	Shiawassee
Grand Traverse	Lenawee	Wexford
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	~~Ionia~~	MONTCALM~~Newaygo~~
Bay	Jackson	Muskegon
Berrien	Kalamazoo	Oakland
Calhoun	Kent	Ottawa
Cass	Lapeer	Saginaw
Clinton	Livingston	St. Clair
Eaton	Macomb	Van Buren
Genesee	MIDLAND	Washtenaw
Ingham	Monroe	Wayne

Source:

~~65~~ 75 F.R., p. ~~82238~~ 37245 (~~December 27~~JUNE 28, ~~2000~~2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR MAGNETIC RESONANCE IMAGING (MRI) SERVICES

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

Section 1. Applicability

Sec. 1. These standards are requirements for the approval of the initiation, expansion, replacement, or acquisition of MRI services and the delivery of services under Part 222 of the Code. Pursuant to Part 222 of the Code, MRI is a covered clinical service. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

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

(a) "Acquisition of an existing MRI service or existing MRI unit(s)" means obtaining control or possession of an existing fixed or mobile MRI service or existing MRI unit(s) by contract, ownership, lease, or other comparable arrangement.

(b) "Actual MRI adjusted procedures" or "MRI adjusted procedures," means the number of MRI procedures, adjusted in accordance with the applicable provisions of Section 15, performed on an existing MRI unit, or if an MRI service has two or more MRI units at the same site, the average number of MRI adjusted procedures performed on each unit, for the 12-month period reported on the most recently published "MRI Service Utilization List," as of the date an application is deemed submitted by the Department.

(c) "Available MRI adjusted procedures" means the number of MRI adjusted procedures performed by an existing MRI service in excess of 8,000 per fixed MRI unit and 7,000 per mobile MRI unit. For either a fixed or mobile MRI service, the number of MRI units used to compute available MRI adjusted procedures shall include both existing and approved but not yet operational MRI units. In determining the number of available MRI adjusted procedures, the Department shall use data for the 12-month period reported on the most recently published list of available MRI adjusted procedures as of the date an application is deemed submitted by the Department.

In the case of a mobile MRI unit, the term means the sum of all MRI adjusted procedures performed by the same mobile MRI unit at all of the host sites combined that is in excess of 7,000. For example, if a mobile MRI unit serves five host sites, the term means the sum of MRI adjusted procedures for all five host sites combined that is in excess of 7,000 MRI adjusted procedures.

(d) "Central service coordinator" means the organizational unit that has operational responsibility for a mobile MRI unit(s).

(e) "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.

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

(g) "Contrast MRI procedure" means an MRI procedure involving either of the following: (i) a procedure following use of a contrast agent or (ii) procedures performed both before and after the use of a contrast agent.

(h) "Dedicated pediatric MRI" means an MRI unit on which at least 80% of the MRI procedures are performed on patients under 18 years of age

(i) "Department" means the Michigan Department of Community Health (MDCH).

(j) "Doctor" means an individual licensed under Article 15 of the Code to engage in the practice of medicine, osteopathic medicine and surgery, chiropractic, dentistry, or podiatry.

(k) "Existing MRI service" means either the utilization of a CON-approved and operational MRI unit(s) at one site in the case of a fixed MRI service, and in the case of a mobile MRI service, the utilization of a CON-approved and operational mobile MRI unit(s) at each host site, on the date an application is submitted to the Department.

(l) "Existing MRI unit" means a CON-approved and operational MRI unit used to provide MRI services.

(m) "Expand an existing fixed MRI service" means an increase in the number of fixed MRI units to be operated by the applicant.

(n) "Expand an existing mobile MRI service" means the addition of a mobile MRI unit that will be operated by a central service coordinator that is approved to operate one or more mobile MRI units as of the date an application is submitted to the Department.

(o) "Group practice" means a group practice as defined pursuant to the provisions of 42 U.S.C. 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411, published in the Federal Register on August 14, 1995, or its replacement.

(p) "Health service area" or "HSA" means the geographic areas set forth in Section 21.

(q) "Host site" means the site at which a mobile MRI unit is authorized by CON to provide MRI services.

(r) "Initiate a fixed MRI service" means begin operation of a fixed MRI service at a site that does not provide or is not CON approved to provide fixed MRI services as of the date an application is submitted to the Department. The term does not include the acquisition or replacement of an existing fixed MRI service to a new site or the renewal of a lease.

(s) "Initiate a mobile MRI host site" means the provision of MRI services at a host site that has not received any MRI services within 12 months from the date an application is submitted to the Department. The term does not include the renewal of a lease.

(t) "Initiate a mobile MRI service" means begin operation of a mobile MRI unit that serves two or more host sites.

The term does not include the acquisition of an existing mobile MRI service or the renewal of a lease.

(u) "Inpatient" means an MRI visit involving an individual who has been admitted to the licensed hospital at the site of the MRI service/unit or in the case of an MRI unit that is not located at that licensed hospital site, an admitted patient transported from a licensed hospital site by ambulance to the MRI service.

(v) "Institutional review board" or "IRB" means an institutional review board as defined by Public Law 93-348 that is regulated by Title 45 CFR 46.

(w) "Intra-operative magnetic resonance imaging" or "IMRI" means the integrated use of MRI technology during surgical and interventional procedures within a licensed operative environment.

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

(y) "Magnetic resonance imaging" or "MRI" means the analysis of the interaction that occurs between radio frequency energy, atomic nuclei, and strong magnetic fields to produce cross sectional images similar to those displayed by computed tomography (CT) but without the use of ionizing radiation.

(z) "MRI adjusted procedure" means an MRI visit, at an existing MRI service, that has been adjusted in accordance with the applicable provisions of Section 15.

(aa) "MRI database" means the database, maintained by the Department pursuant to Section 14 of these standards, that collects information about each MRI visit at MRI services located in Michigan.

(bb) "MRI-guided electrophysiology intervention" or "MRI-guided EPI" means equipment specifically designed for the integrated use of MRI technology for the purposes of electrophysiology interventional procedures within a cardiac catheterization lab.

(cc) "MRI procedure" means a procedure conducted by an MRI unit approved pursuant to sections 3, 4, 5, 6, 7, or 9 of these standards which is either a single, billable diagnostic magnetic resonance procedure or a procedure conducted by an MRI unit at a site participating with an approved diagnostic

radiology residency program, under a research protocol approved by an IRB. The capital and operating costs related to the research use are charged to a specific research account and not charged to or collected from third-party payors or patients. The term does not include a procedure conducted by an MRI unit approved pursuant to Section 7.

(dd) "MRI services" means either the utilization of an authorized MRI unit(s) at one site in the case of a fixed MRI service or in the case of a mobile MRI service, the utilization of an authorized mobile MRI unit at each host site.

(ee) "MRI unit" means the magnetic resonance system consisting of an integrated set of machines and related equipment necessary to produce the images and/or spectroscopic quantitative data from scans including FDA-approved positron emission tomography (PET)/MRI scanner hybrids if used for MRI only procedures. The term does not include MRI simulators used solely for treatment planning purposes in conjunction with a Megavoltage Radiation Therapy (MRT) unit.

(ff) "MRI visit" means a single patient visit to an MRI service/unit that may involve one or more MRI procedures.

(gg) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396g and 1396i to 1396u.

~~(hh) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~

~~(ii) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~

(~~jj~~ii) "Mobile MRI unit" means an MRI unit operating at two or more host sites and that has a central service coordinator. The mobile MRI unit shall operate under a contractual agreement for the provision of MRI services at each host site on a regularly scheduled basis.

(~~kk~~jj) "Ownership interest, direct or indirect" means a direct ownership relationship between a doctor and an applicant entity or an ownership relationship between a doctor and an entity that has an ownership relationship with an applicant entity.

(~~ll~~kk) "Pediatric patient" means a patient who is 12 years of age or less, except for Section 8.

(~~mm~~ll) "Planning area" means

(i) in the case of a proposed fixed MRI service or unit, the geographic area within a 20-mile radius from the proposed site if the proposed site is not in a rural or micropolitan statistical area county and a 75-mile radius from the proposed site if the proposed site is in a rural or micropolitan statistical area county.

(ii) in the case of a proposed mobile MRI service or unit, except as provided in subsection (iii), the geographic area within a 20-mile radius from each proposed host site if the proposed site is not in a rural or micropolitan statistical area county and within a 75-mile radius from each proposed host site if the proposed site is in a rural or micropolitan statistical area county.

(iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section 15(2)(d), the health service area in which all the proposed mobile host sites will be located.

(~~nn~~mm) "Referring doctor" means the doctor of record who ordered the MRI procedure(s) and either to whom the primary report of the results of an MRI procedure(s) is sent or in the case of a teaching facility, the attending doctor who is responsible for the house officer or resident that requested the MRI procedure.

(~~oo~~nn) "Renewal of a lease" means extending the effective period of a lease for an existing MRI unit that does not involve either replacement of the MRI unit, as defined in Section 4, or (ii) a change in the parties to the lease.

(~~pp~~oo) "Research scan" means an MRI scan administered under a research protocol approved by the applicant's IRB.

(~~qq~~pp) "Re-sedated patient" means a patient, either pediatric or adult, who fails the initial sedation during the scan time and must be extracted from the unit to rescue the patient with additional sedation.

~~(rr) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and~~

~~micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~

(~~ss~~qq) "Sedated patient" means a patient that meets all of the following:

(i) whose level of consciousness is either conscious-sedation or a higher level of sedation, as defined by the American Association of Anesthesiologists, the American Academy of Pediatrics, the Joint Commission on the Accreditation of Health Care Organizations, or an equivalent definition.

(ii) who is monitored by mechanical devices while in the magnet.

(iii) who requires observation while in the magnet by personnel, other than employees routinely assigned to the MRI unit, who are trained in cardiopulmonary resuscitation (CPR).

(~~tt~~rr) "Site" means

(i) in the case of a licensed hospital site, a location that is part of the licensed hospital site or a location that is contiguous to the licensed hospital site or

(ii) in the case of a location that is not a licensed hospital site, a location at the same address or a location that is contiguous to that address.

(~~uu~~ss) "Special needs patient" means a non-sedated patient, either pediatric or adult, with any of the following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD), developmental delay, malformation syndromes, hunter's syndrome, multi-system disorders, psychiatric disorders, and other conditions that make the patient unable to comply with the positional requirements of the exam.

(~~vv~~tt) "Teaching facility" means a licensed hospital site, or other location, that provides either fixed or mobile MRI services and at which residents or fellows of a training program in diagnostic radiology, that is approved by the Accreditation Council on Graduate Medical Education or American Osteopathic Association, are assigned.

(~~ww~~uu) "Unadjusted MRI scan" means an MRI procedure performed on a single anatomical site as defined by the MRI database and that is not adjusted pursuant to the applicable provisions of Section 15.

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

Section 3. Requirements to initiate an MRI service

Sec. 3. An applicant proposing to initiate an MRI service or a host site shall demonstrate the following requirements, as applicable:

(1) An applicant proposing to initiate a fixed MRI service shall demonstrate 6,000 available MRI adjusted procedures per proposed fixed MRI unit from within the same planning area as the proposed service/unit.

(2) An applicant proposing to initiate a fixed MRI service that meets the following requirements shall not be required to be in compliance with subsection (1):

(a) The applicant is currently an existing host site.

(b) The applicant has received in aggregate, one of the following:

(i) At least 6,000 MRI adjusted procedures.

(ii) At least 4,000 MRI adjusted procedures and the applicant meets all of the following:

(A) Is located in a county that has no fixed MRI machines that are pending, approved by the Department, or operational at the time the application is deemed submitted.

(B) The nearest fixed MRI machine is located more than 15 radius miles from the application site.

(iii) At least 3,000 MRI adjusted procedures and the applicant meets all of the following:

(A) The proposed site is a hospital licensed under Part 215 of the Code.

(B) The applicant hospital operates an emergency room that provides 24-hour emergency care services and at least 20,000 visits within the most recent 12-month period for which data, verifiable by the Department, is available.

(c) All of the MRI adjusted procedures from the mobile MRI service referenced in Section 3(2)(b) shall be utilized even if the aggregated data exceeds the minimum requirements.

(d) The applicant shall install the fixed MRI unit at the same site as the existing host site or within the relocation zone. If applying pursuant to Section 3(2)(b)(iii), the applicant shall install the fixed MRI unit at the same site as the existing host site.

(e) The applicant shall cease operation as a host site and not become a host site for at least 12 months from the date the fixed service and its unit becomes operational.

(3) An applicant proposing to initiate a mobile MRI service shall demonstrate 5,500 available MRI adjusted procedures from within the same planning area as the proposed service/unit, and the applicant shall meet the following:

(a) Identify the proposed route schedule and procedures for handling emergency situations.

(b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI service.

(c) Identify a minimum of two (2) host sites for the proposed service.

(4) An applicant, whether the central service coordinator or the host site, proposing to initiate a host site on a new or existing mobile MRI service shall demonstrate the following, as applicable:

(a) 600 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, for a proposed host site that is not located in a rural or micropolitan statistical area county, or

(b) 400 available MRI adjusted procedures from within the same planning area for a proposed host site that is located in a rural or micropolitan statistical area county, and

(c) The proposed host site has not received any mobile MRI service within the most recent 12-month period as of the date an application is submitted to the Department.

(5) An applicant proposing to add or change service on an existing mobile MRI service that meets the following requirements shall not be required to be in compliance with subsection (4):

(a) The host site has received mobile MRI services from an existing mobile MRI unit within the most recent 12-month period as of the date an application is submitted to the Department.

(b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI service.

(6) The applicant shall demonstrate that the available MRI adjusted procedures from the "Available MRI Adjusted Procedures List" or the adjusted procedures from the "MRI Service Utilization List," as applicable, are from the most recently published MRI lists as of the date an application is deemed submitted by the Department.

Section 4. Requirements to replace an existing MRI unit

Sec. 4. Replace an existing MRI unit means (i) any equipment change involving a change in, or replacement of, the entire MRI unit resulting in an applicant operating the same number and type (fixed or mobile) of MRI units before and after project completion or (ii) an equipment change that involves a capital expenditure of $750,000 or more in any consecutive 24-month period or (iii) the renewal of a lease. Replacement also means the relocation of an MRI service or unit to a new site. The term does not include the replacement of components of the MRI system, including the magnet, under an existing service contract or required maintenance to maintain the system to operate within manufacturer specifications. The term does not include an upgrade to an existing MRI unit or repair of an existing MRI service or unit, and it does not include a host site that proposes to receive mobile MRI services from a different central service coordinator if the requirements of Section 3(5) have been met.

(1) "Upgrade an existing MRI unit" means any equipment change that

(i) does not involve a change in, or replacement of, the entire MRI unit, does not result in an increase in the number of MRI units; or does not result in a change in the type of MRI unit (e.g., changing a mobile MRI unit to a fixed MRI unit); and

(ii) involves a capital expenditure related to the MRI equipment of less than $750,000 in any consecutive 24-month period.

(2) "Repair an existing MRI unit" means restoring the ability of the system to operate within the manufacturer's specifications by replacing or repairing the existing components or parts of the system, including the magnet, pursuant to the terms of an existing maintenance agreement that does not result in a change in the strength of the MRI unit.

(3) An applicant proposing to replace an existing MRI unit shall demonstrate the following requirements, as applicable:

(a) An applicant shall demonstrate that the applicable MRI adjusted procedures are from the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department. An applicant proposing to replace an existing MRI unit that is below 1 tesla with an MRI unit that is a 1 tesla or higher, shall be exempt once, as of September 18, 2013, from the minimum volume requirements for replacement:

(i) Each existing mobile MRI unit on the network has performed at least an average of 5,500 MRI adjusted procedures per MRI unit.

(ii) Each existing fixed MRI unit at the current site has performed at least an average of 6,000 MRI adjusted procedures per MRI unit unless the applicant demonstrates compliance with one of the following:

(A) The existing fixed MRI unit initiated pursuant to Section 3(2)(b)(ii) has performed at least 4,000 MRI adjusted procedures and is the only fixed MRI unit at the current site.

(B) The existing fixed MRI unit initiated pursuant to Section 3(2)(b)(iii) has performed at least 3,000 MRI adjusted procedures and is the only fixed MRI unit at the current site.

(iii) Each existing dedicated pediatric MRI unit at the current site has performed at least an average of 3,500 MRI adjusted procedures per MRI unit.

(b) 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.

(c) The replacement unit shall be located at the same site.

(d) An applicant proposing to replace an existing MRI unit that does not involve a renewal of a lease shall demonstrate that the MRI unit to be replaced is fully depreciated according to generally accepted accounting principles; the existing equipment clearly poses a threat to the safety of the public; or the proposed replacement equipment offers a significant technological improvement which enhances quality of care, increases efficiency, and reduces operating costs.

(4) An applicant proposing to replace an existing mobile MRI host site to a new location shall demonstrate the following:

(a) The applicant currently operates the MRI mobile host site to be relocated.

(b) The MRI mobile host site to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.

(c) The proposed new site is within a 5-mile radius of the existing site for a metropolitan statistical area county or within a 10-mile radius for a rural or micropolitan statistical area county.

(d) The mobile MRI host site to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.

(e) The relocation will not involve a change in the current central service coordinator unless the requirements of Section 3(5) are met.

(5) An applicant proposing to replace an existing fixed MRI service and its unit(s) to a new site shall demonstrate the following:

(a) The existing MRI service and its unit(s) to be replaced has been in operation for at least 36 months as of the date an application is submitted to the Department.
(b) The proposed new site is within a 10-mile radius of the existing site.
(c) Each existing MRI unit to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.

(6) An applicant proposing to replace a fixed MRI unit of an existing MRI service to a new site shall demonstrate the following:
(a) The applicant currently operates the MRI service from which the unit will be relocated.
(b) The existing MRI service from which the MRI unit(s) to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.
(c) The proposed new site is within a 10-mile radius of the existing site.
(d) Each existing MRI unit at the service from which a unit is to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.
(e) For volume purposes, the new site shall remain associated to the original site for a minimum of three years.

Section 5. Requirements to expand an existing MRI service

Sec. 5. An applicant proposing to expand an existing MRI service shall demonstrate the following:

(1) An applicant shall demonstrate that the applicable MRI adjustable procedures are from the most recently published MRI Service Utilization List as of the date of an application is deemed submitted by the Department:
(a) Each existing MRI unit on the network has performed at least an average of 9,000 MRI adjusted procedures per MRI unit.
(b) Each existing fixed MRI unit at the current site has performed at least an average of 11,000 MRI adjusted procedures per MRI unit.
(c) Each existing dedicated pediatric MRI unit at the current site has performed at least an average of 3,500 MRI adjusted procedures per MRI unit.

(2) The additional fixed unit shall be located at the same site unless the requirements of the replacement section have been met.

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

Sec. 6. (1) An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s) shall demonstrate the following:
(a) For the first application proposing to acquire an existing fixed or mobile MRI service on or after July 1, 1997, the existing MRI service and its unit(s) to be acquired shall not be required to be in compliance with the volume requirements applicable to a seller/lessor on the date the acquisition occurs. The MRI service shall be operating at the applicable volume requirements set forth in Section 14 of these standards in the second 12 months after the effective date of the acquisition, and annually thereafter.
(b) For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s), except the first application approved pursuant to subsection (a), an applicant shall be required to document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume requirements set forth in Section 14 of these standards applicable to an existing MRI service on the date the application is submitted to the Department.

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

(a) The project will not change the number of MRI units at the site of the MRI service being acquired, subject to the applicable requirements under Section 4(6), unless the applicant demonstrates that the project is in compliance with the requirements of the initiation or expansion Section, as applicable.

(b) The project will not result in the replacement of an MRI unit at the MRI service to be acquired unless the applicant demonstrates that the requirements of the replacement section have been met.

Section 7. Requirements to establish a dedicated research MRI unit

Sec. 7. An applicant proposing an MRI unit to be used exclusively for research shall demonstrate the following:

(1) The applicant agrees that the dedicated research MRI unit will be used primarily (70% or more of the procedures) for research purposes only.

(2) Submit copies of documentation demonstrating that the applicant operates a diagnostic radiology residency program approved by the Accreditation Council for Graduate Medical Education, the American Osteopathic Association, or an equivalent organization.

(3) Submit copies of documentation demonstrating that the MRI unit shall operate under a protocol approved by the applicant's IRB.

(4) An applicant meeting the requirements of this section shall be exempt from meeting the requirements of sections to initiate and replace.

Section 8. Requirements to establish a dedicated pediatric MRI unit

Sec. 8. An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the following:

(1) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges (excluding normal newborns) in the most recent year of operation.

(2) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the most recent year of operation.

(3) The applicant shall have an active medical staff that includes, but is not limited to, physicians who are fellowship-trained in the following pediatric specialties:

(a) pediatric radiology (at least two)
(b) pediatric anesthesiology
(c) pediatric cardiology
(d) pediatric critical care
(e) pediatric gastroenterology
(f) pediatric hematology/oncology
(g) pediatric neurology
(h) pediatric neurosurgery
(i) pediatric orthopedic surgery
(j) pediatric pathology
(k) pediatric pulmonology
(l) pediatric surgery
(m) neonatology

(4) The applicant shall have in operation the following pediatric specialty programs:
(a) pediatric bone marrow transplant program
(b) established pediatric sedation program
(c) pediatric open heart program

(5) An applicant meeting the requirements of this section shall be exempt from meeting the requirements of Section 5 of these standards.

Section 9. Requirements for all applicants proposing to initiate, replace, or acquire a hospital based IMRI

Sec. 9. An applicant proposing to initiate, replace, or acquire a hospital based IMRI service shall demonstrate each of the following, as applicable to the proposed project.

(1) The proposed site is a licensed hospital under Part 215 of the Code.

(2) The proposed site has an existing fixed MRI service that has been operational for the previous 36 consecutive months and is meeting its minimum volume requirements.

(3) The proposed site has an existing and operational surgical service and is meeting its minimum volume requirements pursuant to the CON Review Standards for Surgical Services.

(4) The applicant has achieved one of the following:
(a) at least 1,500 oncology discharges in the most recent year of operation; or
(b) at least 1,000 neurological surgeries in the most recent year of operation; or
(c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.

(5) The proposed IMRI unit must be located in an operating room or a room adjoining an operating room allowing for transfer of the patient between the operating room and this adjoining room.

(6) Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under this section unless the patient meets one of the following criteria:
(a) the patient has been admitted to an inpatient unit; or
(b) the patient is having the study performed on an outpatient basis, but is in need of general anesthesia or deep sedation as defined by the American Society of Anesthesiologists.

(7) The approved IMRI unit will not be subject to MRI volume requirements.

(8) The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need or to satisfy MRI CON review standards requirements.

Section 10. Requirements for all applicants proposing to initiate, replace, or acquire a hospital based MRI-guided EPI service

Sec. 10. An applicant proposing to initiate, replace, or acquire a hospital based MRI-guided EPI service shall demonstrate each of the following, as applicable to the proposed project.

(1) The proposed site is a licensed hospital under part 215 of the Code.

(2) The proposed site has an existing fixed MRI service that has been operational for the previous 36 consecutive months and is meeting its minimum volume requirements.

(3) The proposed site has an existing and operational therapeutic cardiac catheterization service and is meeting its minimum volume requirements pursuant to the CON review standards for cardiac catheterization services and open heart surgery services.

(4) The proposed MRI-guided EPI unit must be located in a cardiac catheterization lab containing a flouroscopy unit with an adjoining room containing an MRI scanner. The rooms shall contain a patient transfer system allowing for transfer of the patient between the cardiac catheterization lab and the MRI unit, utilizing one of the following:

(a) moving the patient to the MRI scanner, or

(b) installing the MRI scanner on a sliding gantry to allow the patient to remain stationary.

(5) Non-cardiac MRI diagnostic studies shall not be performed in an MRI-guided EPI unit approved under this section unless the patient meets one of the following criteria:

(a) The patient has been admitted to an inpatient unit; or

(b) The patient is having the study performed on an outpatient basis as follows:

(i) is in need of general anesthesia or deep sedation as defined by the American Society of Anesthesiologists, or

(ii) has an implantable cardiac device.

(6) The approved MRI-guided EPI unit shall not be subject to MRI volume requirements.

(7) The applicant shall not utilize the procedures performed on the MRI-guided EPI unit to demonstrate need or to satisfy MRI CON review standards requirements.

Section 11. Requirements for all applicants proposing to initiate, replace, or acquire an MRI simulator that will not be used solely for MRT treatment planning purposes

Sec. 11. MRI simulation is the use of MRI to help simulate (or plan) a patient's MRT treatment and to incorporate superior delineation of soft tissues for MRT treatment plans. An applicant proposing to initiate, replace, or acquire an MRI simulator shall demonstrate each of the following, as applicable to the proposed project.

(1) The proposed site has an existing fixed MRI service that has been operational for the previous 36 consecutive months and is meeting its minimum volume requirements.

(2) The proposed site has an existing and operational MRT service and is meeting its minimum volume requirements pursuant to the CON review standards for MRT services/units.

(3) MRI diagnostic studies shall not be performed using an MRI simulator approved under this section unless the patient meets one of the following criteria:

(a) The patient has been admitted to an inpatient unit; or

(B) The patient is having the study performed on an outpatient basis, but is in need of general anesthesia or deep sedation as defined by the American Society of Anesthesiologists.

(4) The approved MRI simulator will not be subject to MRI volume requirements.

(5) The applicant shall not utilize the procedures performed on the MRI simulator to demonstrate need or to satisfy MRI CON review standards requirements.

Section 12. Requirements for approval of an FDA-approved PET/MRI scanner hybrid for initiation, expansion, replacement, and acquisition

Sec. 12. An applicant proposing to initiate, expand, replace, or acquire an FDA-approved PET/MRI scanner hybrid shall demonstrate that it meets all of the following:

(1) There is an approved PET CON for the FDA-approved PET/MRI hybrid, and the FDA-approved PET/MRI scanner hybrid is in compliance with all applicable project delivery requirements as set forth in the CON review standards for PET.

(2) The applicant agrees to operate the FDA-approved PET/MRI scanner hybrid in accordance with all applicable project delivery requirements set forth in Section 14 of these standards.

(3) The approved FDA-approved PET/MRI scanner hybrid shall not be subject to MRI volume requirements.

(4) An FDA-approved PET/MRI scanner hybrid approved under the CON review standards for PET scanner services and the review standards for MRI scanner services may not utilize MRI procedures performed on an FDA-approved PET/MRI scanner hybrid to demonstrate need or to satisfy MRI CON review standards requirements.

Section 13. Requirements for all applicants

Sec. 13. 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 14. Project delivery requirements – terms of approval

Sec. 14. An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall be delivered and maintained in compliance with the following:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) An applicant shall develop and maintain policies and procedures that establish protocols for assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI service.

(b) An applicant shall establish a schedule for preventive maintenance for the MRI unit.

(c) An applicant shall provide documentation identifying the specific individuals that form the MRI team. At a minimum, the MRI team shall consist of the following professionals:

(i) Physicians who shall be responsible for screening of patients to assure appropriate utilization of the MRI service and taking and interpretation of scans. At least one of these physicians shall be a board-certified radiologist.

(ii) An appropriately trained MRI technician who shall be responsible for taking an MRI scan.

(iii) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual basis.

(d) An applicant shall document that the MRI team members have the following qualifications:

(i) Each physician credentialed to interpret MRI scans meets the requirements of each of the following:

(A) The physician is licensed to practice medicine in the State of Michigan.

(B) The physician has had at least 60 hours of training in MRI physics, MRI safety, and MRI instrumentation in a program that is part of an imaging program accredited by the Accreditation Council for

Graduate Medical Education or the American Osteopathic Association, and the physician meets the requirements of subdivision (1), (2), or (3):

(1) Board certification by the American Board of Radiology, the American Osteopathic Board of Radiology, or the Royal College of Physicians and Surgeons of Canada. If the diagnostic radiology program completed by a physician in order to become board certified did not include at least two months of MRI training, that physician shall document that he or she has had the equivalent of two months of postgraduate training in clinical MRI imaging at an institution which has a radiology program accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association.

(2) Formal training by an imaging program(s), accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association that included two years of training in cross-sectional imaging and six months training in organ-specific imaging areas.

(3) A practice in which at least one-third of total professional time, based on a full-time clinical practice during the most recent 5-year period, has been the primary interpretation of MR imaging.

(C) The physician has completed and will complete a minimum of 40 hours every two years of Category in Continuing Medical Education credits in topics directly involving MR imaging.

(D) The physician complies with the “American College of Radiology (ACR) Practice Guideline for Performing and Interpreting Magnetic Resonance Imaging (MRI).”

(ii) An MRI technologist who is registered by the American Registry of Radiologic Technicians or by the American Registry of Magnetic Resonance Imaging Technologists (ARMRIT) and has, or will have within 36 months of the effective date of these standards or the date a technologist is employed by an MRI service, whichever is later, special certification in MRI. If a technologist does not have special certification in MRI within either of the 3-year periods of time, all continuing education requirements shall be in the area of MRI services.

(iii) An applicant shall document that an MRI physicist/engineer is appropriately qualified. For purposes of evaluating this subdivision, the Department shall consider it prima facie evidence as to the qualifications of the physicist/engineer if the physicist/engineer is certified as a medical physicist by the American Board of Radiology, the American Board of Medical Physics, or the American Board of Science in Nuclear Medicine. However, the applicant may submit and the Department may accept other evidence that an MRI physicist/engineer is qualified appropriately.

(e) The applicant shall have, within the MRI unit/service, equipment and supplies to handle clinical emergencies that might occur in the unit. MRI service staff will be trained in CPR and other appropriate emergency interventions. A physician shall be on-site, in, or immediately available to the MRI unit at all times when patients are undergoing scans.

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

The applicant, to assure that the MRI unit will be utilized by all segments of the Michigan population, shall

(a) provide MRI services to all individuals based on the clinical indications of need for the service and not on ability to pay or source of payment.

(b) maintain information by source of payment to indicate the volume of care from each source provided annually.

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

(d) The operation of and referral of patients to the MRI unit 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) MRI units shall be operating at a minimum average annual utilization during the second 12 months of operation, and annually thereafter, as applicable:

(i) 6,000 MRI adjusted procedures per unit for fixed MRI services unless compliant with (1) or (2),

(A) 4,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(ii) and is the only fixed MRI unit at the current site,

(B) 3,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(iii) and is the only fixed MRI unit at the hospital site licensed under part 215 of the code,

(ii) 5,500 MRI adjusted procedures per unit for mobile MRI services.
(iii) 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI units.
(iv) Each mobile host site in a rural or micropolitan statistical area county shall have provided at least a total of 400 adjusted procedures during its second 12 months of operation, and annually thereafter, from all mobile units providing services to the site. Each mobile host site not in a rural or micropolitan statistical area county shall have provided at least a total of 600 adjusted procedures during its second 12 months of operation and annually thereafter, from all mobile units providing services to the site.
(v) In meeting these requirements, an applicant shall not include any MRI adjusted procedures performed on an MRI unit used exclusively for research and approved pursuant to Section 7 or for an IMRI unit approved pursuant to Section 9.

(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, operating schedules, demographic and diagnostic information, and the volume of care provided to patients from all payor sources, as well as other data requested by the Department or its designee and approved by the Commission. The applicant shall provide the required data in a format established by the Department and in a mutually agreed upon media no later than 30 days following the last day of the quarter for which data are being reported to the Department. An applicant shall be considered in violation of this term of approval if the required data are not submitted to the Department within 30 days following the last day of the quarter for which data are being reported. The Department may elect to verify the data through on-site review of appropriate records. Data for an MRI unit approved pursuant to Section 7, Section 8, Section 9, Section 10, or Section 11 shall be reported separately.
For purposes of Section 9, the data reported shall include, at a minimum, how often the IMRI unit is used and for what type of services, i.e., intra-operative or diagnostic. For purposes of Section 10, the data reported shall include, at a minimum, how often the MRI-guided EPI unit is used and for what type of services, i.e., electrophysiology or diagnostic. For purposes of Section 11, the data reported shall include, at a minimum, how often the MRI simulator is used and for what type of services, i.e., treatment plans or diagnostic services.
(c) The applicant shall provide the Department with a notice stating the first date on which the MRI unit became operational, and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.
(d) An applicant who is a central service coordinator shall notify the Department of any additions, deletions, or changes in the host sites of each approved mobile MRI unit within 10 days after the change(s) in host sites is made.

(5) An applicant for an MRI unit approved under Section 7 shall agree that the services provided by the MRI unit are delivered in compliance with the following terms.
(a) The capital and operating costs relating to the research use of the MRI unit shall be charged only to a specific research account(s) and not to any patient or third-party payor.
(b) The MRI unit shall not be used for any purposes other than as approved by the IRB unless the applicant has obtained CON approval for the MRI unit pursuant to Part 222 and these standards, other than Section 7.
(c) The dedicated research MRI unit will be used primarily (70% or more of the procedures) for research purposes only.

(6) The dedicated pediatric MRI unit approved under Section 8 shall include at least 80% of the MRI procedures that are performed on patients under 18 years of age.

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

Section 15. MRI procedure adjustments

Sec. 15. (1) The Department shall apply the following formula, as applicable, to determine the number of MRI adjusted procedures that are performed by an existing MRI service or unit:

(a) The base value for each MRI procedure is 1.0. For functional MRI (fMRI) procedures, MRI-guided interventions, and cardiac MRI procedures, the base value is 2.0.

(i) fMRI means brain activation studies.

(ii) MRI-guided interventions means any invasive procedure performed requiring MRI guidance performed in the MRI scanner.

(iii) Cardiac MRI Procedure means dedicated MRI performed of the heart done for the sole purpose of evaluation of cardiac function, physiology, or viability.

(b) For each MRI visit involving a pediatric patient, 0.25 shall be added to the base value.

(c) For each MRI visit involving an inpatient, 0.50 shall be added to the base value.

(d) For each MRI procedure performed on a sedated patient, 0.75 shall be added to the base value.

(e) For each MRI procedure performed on a re-sedated patient, 0.25 shall be added to the base value.

(f) For each MRI procedure performed on a special needs patient, 0.25 shall be added to the base value.

(g) For each MRI visit that involves both a clinical and research scan on a single patient in a single visit, 0.25 shall be added to the base value.

(h) For each contrast MRI procedure performed after use of a contrast agent, and not involving a procedure before use of a contrast agent, 0.35 shall be added to the base value.

(i) For each contrast MRI procedure involving a procedure before and after use of a contrast agent, 1.0 shall be added to the base value.

(j) For each MRI procedure performed at a teaching facility, 0.15 shall be added to the base value.

(k) The results of subsections (a) through (j) shall be summed, and that sum shall represent an MRI adjusted procedure.

(2) The Department shall apply not more than one of the adjustment factors set forth in this subsection, as applicable, to the number of MRI procedures adjusted in accordance with the applicable provisions of subsection (1) that are performed by an existing MRI service or unit.

(a) For a site located in a rural or micropolitan statistical area county, the number of MRI adjusted procedures shall be multiplied by a factor of 1.4.

(b) For a mobile MRI unit that serves hospitals and other host sites located in rural, micropolitan statistical area, and metropolitan statistical area counties, the number of MRI adjusted procedures for a site located in a rural or micropolitan statistical area county, shall be multiplied by a factor of 1.4 and for a site located in a metropolitan statistical area county, the number of MRI adjusted procedures shall be multiplied by a factor of 1.0.

(c) For a mobile MRI unit that serves only sites located in rural or micropolitan statistical area counties, the number of MRI adjusted procedures shall be multiplied by a factor of 2.0.

(d) For a mobile MRI unit that serves only sites located in a health service area with one or fewer fixed MRI units and one or fewer mobile MRI units, the number of MRI adjusted procedures shall be multiplied by a factor of 3.5.

(e) Subsection (2) shall not apply to an application proposing a subsequent fixed MRI unit (second, third, etc.) at the same site.

(3) The number of MRI adjusted procedures performed by an existing MRI service is the sum of the results of subsections (1) and (2).

Section 16. Documentation of actual utilization

Sec. 16. Documentation of the number of MRI procedures performed by an MRI unit shall be substantiated by the Department utilizing data submitted by the applicant in a format and media specified

by the Department and as verified for the 12-month period reported on the most recently published "MRI Service Utilization List" as of the date an application is deemed submitted by the Department. The number of MRI procedures actually performed shall be documented by procedure records and not by application of the methodology required in Section 17. The Department may elect to verify the data through on-site review of appropriate records.

Section 17. Methodology for computing the number of available MRI adjusted procedures

Sec. 17. (1) The number of available MRI adjusted procedures required pursuant to Section 3 shall be computed in accordance with the methodology set forth in this section. In applying the methodology, the following steps shall be taken in sequence, and data for the 12-month period reported on the most recently published "Available MRI Adjusted Procedures List," as of the date an application is deemed submitted by the Department, shall be used:

(a) Identify the number of actual MRI adjusted procedures performed by each existing MRI service as determined pursuant to Section 15.

(i) For purposes of computing actual MRI adjusted procedures, MRI adjusted procedures performed on MRI units used exclusively for research and approved pursuant to Section 7 and dedicated pediatric MRI approved pursuant to Section 8 shall be excluded.

(ii) For purposes of computing actual MRI adjusted procedures, the MRI adjusted procedures, from the host site routes utilized to meet the requirements of Section 3(2)(c), shall be excluded beginning at the time the application is submitted and for three years from the date the fixed MRI unit becomes operational.

(iii) For purposes of computing actual MRI adjusted procedures, the MRI adjusted procedures utilized to meet the requirements of Section 5(1) shall be reduced by 8,000 and shall be excluded beginning at the time the application is submitted and for three years from the date the fixed MRI unit becomes operational.

(b) Identify the number of available MRI adjusted procedures, if any, for each existing MRI service as determined pursuant to Section 2(1)(c).

(c) Determine the number of available MRI adjusted procedures that each referring doctor may commit from each service to an application in accordance with the following:

(i) Divide the number of available MRI adjusted procedures identified in subsection (b) for each service by the number of actual MRI adjusted procedures identified in subsection (a) for that existing MRI service.

(ii) For each doctor referring to that existing service, multiply the number of actual MRI adjusted procedures that the referring doctor made to the existing MRI service by the applicable proportion obtained by the calculation in subdivision (c)(i).

(A) For each doctor, subtract any available adjusted procedures previously committed. The total for each doctor cannot be less than zero.

(B) The total number of available adjusted procedures for that service shall be the sum of the results of (A) above.

(iii) For each MRI service, the available MRI adjusted procedures resulting from the calculation in (c)(ii) above shall be sorted in descending order by the available MRI adjusted procedures for each doctor. Then any duplicate values shall be sorted in descending order by the doctors' license numbers (last 6 digits only).

(iv) Using the data produced in (c)(iii) above, sum the number of available adjusted procedures in descending order until the summation equals at least 75 percent of the total available adjusted procedures. This summation shall include the minimum number of doctors necessary to reach the 75 percent level.

(v) For the doctors representing 75 percent of the total available adjusted procedures in (c)(iv) above, sum the available adjusted procedures.

(vi) For the doctors used in subsection (c)(v) above, divide the total number of available adjusted procedures identified in (c)(ii)(B) above by the sum of those available adjusted procedures produced in (c)(v) above.

(vii) For only those doctors identified in (c)(v) above, multiply the result of (c)(vi) above by the available adjusted procedures calculated in (c)(ii)(A) above.

(viii) The result shall be the “Available MRI Adjusted Procedures List.”

(2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON applications received in which applicants apply for fixed MRI services pursuant to Section 3(2).

Section 18. Procedures and requirements for commitments of available MRI adjusted procedures

Sec. 18. (1) If one or more host sites on a mobile MRI service are located within the planning area of the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile MRI service.

(2)(a) At the time the application is submitted to the Department, the applicant shall submit a signed data commitment on a form provided by the Department in response to the applicant’s letter of intent for each doctor committing available MRI adjusted procedures to that application for a new MRI unit that requires doctor commitments.

(b) An applicant also shall submit, at the time the application is submitted to the Department, a computer file that lists, for each MRI service from which data are being committed to the same application, the name and license number of each doctor for whom a signed and dated data commitment form is submitted.

(i) The computer file shall be provided to the Department on mutually agreed upon media and in a format prescribed by the Department.

(ii) If the doctor commitments submitted on the Departmental forms do not agree with the data on the computer file, the applicant shall be allowed to correct only the computer file data which includes adding physician commitments that were submitted at the time of application.

(c) If the required documentation for the doctor commitments submitted under this subsection is not submitted with the application on the designated application date, the application will be deemed submitted on the first applicable designated application date after all required documentation is received by the Department.

(3) The Department shall consider a signed and dated data commitment on a form provided by the Department in response to the applicant’s letter of intent that meets the requirements of each of the following, as applicable:

(a) A committing doctor certifies that 100% of his or her available MRI adjusted procedures for each specified MRI service, calculated pursuant to Section 17, is being committed and specifies the CON application number for the MRI unit to which the data commitment is made. A doctor shall not be required to commit available MRI adjusted procedures from all MRI services to which his or her patients are referred for MRI services but only from those MRI services specified by the doctor in the data commitment form provided by the Department and submitted by the applicant in support of its application.

(b) A committing doctor certifies ownership interest, either direct or indirect, in the applicant entity. Indirect ownership includes ownership in an entity that has ownership interest in the applicant entity. This requirement shall not apply if the applicant entity is a group practice of which the committing doctor is a member. Group practice means a group practice as defined pursuant to the provisions of 42 U.S.C. 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411, published in the Federal Register on August 14, 1995, or its replacement.

(c) A committing doctor certifies that he or she has not been provided, or received a promise of being provided, a financial incentive to commit any of his or her available MRI adjusted procedures to the application.

(4)(a) The Department shall not consider a data commitment from a doctor for available MRI adjusted procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI service were used to support approval of an application for a new or additional MRI unit, pursuant to Section 3, for which a final decision to approve has been issued by the Director of the Department until either of the following occurs:

(i) The approved CON is withdrawn or expires.

(ii) The MRI service or unit to which the data were committed has been in operation for at least 36 continuous months.

(b) The Department shall not consider a data commitment from a doctor for available MRI adjusted procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI service were used to support an application for a new fixed or mobile MRI unit or additional mobile MRI unit pursuant to Section 3, for which a final decision to disapprove was issued by the Director of the Department until either of the following occurs:

(i) A final decision to disapprove an application is issued by the Director and the applicant does not appeal that disapproval or

(ii) If an appeal was made, either that appeal is withdrawn by the applicant or the committing doctor withdraws his or her data commitment pursuant to the requirements of subsection (8).

(5) The Department shall not consider a data commitment from a committing doctor for available MRI adjusted procedures from the same MRI service if that doctor has submitted a signed data commitment, on a form provided by Department, for more than one (1) application for which a final decision has not been issued by the Department. If the Department determines that a doctor has submitted a signed data commitment for the same available MRI adjusted procedures from the same MRI service to more than one CON application pending a final decision for a new fixed or mobile MRI unit or additional mobile MRI unit pursuant to Section 3, the Department shall,

(a) if the applications were submitted on the same designated application date, notify all applicants, simultaneously and in writing, that one or more doctors have submitted data commitments for available MRI adjusted procedures from the same MRI service and that the doctors' data from the same MRI service shall not be considered in the review of any of the pending applications submitted on the same designated application date until the doctor notifies the Department, in writing, of the one (1) application for which the data commitment shall be considered.

(b) if the applications were submitted on different designated application dates, consider the data commitment in the application submitted on the earliest designated application date and shall notify, simultaneously in writing, all applicants of applications submitted on designated application dates subsequent to the earliest date that one or more committing doctors have submitted data commitments for available MRI adjusted procedures from the same MRI service and that the doctors' data shall not be considered in the review of the application(s) submitted on the subsequent designated application date(s).

(6) The Department shall not consider any data commitment submitted by an applicant after the date an application is deemed submitted unless an applicant is notified by the Department, pursuant to subsection (5), that one or more committing doctors submitted data commitments for available MRI adjusted procedures from the same MRI service. If an applicant is notified that one or more doctors' data commitments will not be considered by the Department, the Department shall consider data commitments submitted after the date an application is deemed submitted only to the extent necessary to replace the data commitments not being considered pursuant to subsection (5).

(a) The applicant shall have 30 days to submit replacement of doctor commitments as identified by the Department in this Section.

(7) In accordance with either of the following, the Department shall not consider a withdrawal of a signed data commitment:

(a) on or after the date an application is deemed submitted by the Department.

(b) after a proposed decision to approve an application has been issued by the Department.

(8) The Department shall consider a withdrawal of a signed data commitment if a committing doctor submits a written notice to the Department, that specifies the CON application number and the specific MRI services for which a data commitment is being withdrawn, and if an applicant demonstrates that the requirements of subsection (7) also have been met.

Section 19. Lists published by the Department

Sec. 19. (1) On or before May 1 and November 1 of each year, the Department shall publish the following lists:

(a) A list, known as the "MRI Service Utilization List," of all MRI services in Michigan that includes at least the following for each MRI service:

(i) The number of actual MRI adjusted procedures;

(ii) The number of available MRI adjusted procedures, if any; and

(iii) The number of MRI units, including whether each unit is a clinical, research, or dedicated pediatric.

(b) A list, known as the "Available MRI Adjusted Procedures List," that identifies each MRI service that has available MRI adjusted procedures and includes at least the following:

(i) The number of available MRI adjusted procedures;

(ii) The name, address, and license number of each referring doctor, identified in Section 17(1)(c)(v), whose patients received MRI services at that MRI service; and

(iii) The number of available MRI adjusted procedures performed on patients referred by each referring doctor, identified in Section 17(1)(c)(v), and if any are committed to an MRI service. This number shall be calculated in accordance with the requirements of Section 17(1). A referring doctor may have fractional portions of available MRI adjusted procedures.

(c) For the lists published pursuant to subsections (a) or (b), the May 1 list will report 12 months of data from the previous January 1 through December 31 reporting period, and the November 1 list will report 12 months of data from the previous July 1 through June 30 reporting period. Copies of both lists shall be available upon request.

(d) The Department shall not be required to publish a list that sorts MRI database information by referring doctor, only by MRI service.

(2) When an MRI service begins to operate at a site at which MRI services previously were not provided, the Department shall include in the MRI database, data beginning with the second full quarter of operation of the new MRI service. Data from the start-up date to the start of the first full quarter will not be collected to allow a new MRI service sufficient time to develop its data reporting capability. Data from the first full quarter of operation will be submitted as test data but will not be reported in the lists published pursuant to this section.

(3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported data in compliance with the requirements of Section 14, the Department shall indicate on both lists that the MRI service is in violation of the requirements set forth in Section 14, and no data will be shown for that service on either list.

Section 20. Effect on prior CON Review Standards; Comparative reviews

Sec. 20. (1) These CON review standards supersede and replace the CON Review Standards for MRI Services approved by the CON Commission on June ~~14~~13, ~~2012~~ 2013 and effective September ~~28~~18, ~~2012~~2013.

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

Section 21. Health Service Areas

Sec. 21. Counties assigned to each of the health service areas are as follows:

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

APPENDIX A

~~CON REVIEW STANDARDS~~ ~~FOR MRI SERVICES~~

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

Allegan	HILLSDALE	MASON
Alpena	Houghton	Mecosta
Benzie	IONIA	Menominee
Branch	Isabella	~~Midland~~
Chippewa	Kalkaska	Missaukee
Delta	Keweenaw	St. Joseph
Dickinson	Leelanau	Shiawassee
Grand Traverse	Lenawee	Wexford
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	~~Ionia~~	MONTCALM~~Newaygo~~
Bay	Jackson	Muskegon
Berrien	Kalamazoo	Oakland
Calhoun	Kent	Ottawa
Cass	Lapeer	Saginaw
Clinton	Livingston	St. Clair
Eaton	Macomb	Van Buren
Genesee	MIDLAND	Washtenaw
Ingham	Monroe	Wayne

Source:

~~65~~ 75 F.R., p. ~~82238~~ 37245 (~~December 27~~JUNE 28, ~~2000~~2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED REVIEW (CON) STANDARDS FOR NEONATAL INTENSIVE CARE SERVICES/BEDS AND SPECIAL NEWBORN NURSING SERVICES

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

Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval of the initiation, replacement, relocation, expansion, or acquisition of neonatal intensive care services/beds and the delivery of neonatal intensive care services/beds under Part 222 of the Code. Further, these standards are requirements for the approval of the initiation or acquisition of special care nursery (SCN) services. Pursuant to Part 222 of the Code, neonatal intensive care services/beds and special newborn nursing services are covered clinical services. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

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

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

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

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

(d) "Department" means the Michigan Department of Community Health (MDCH).

(e) "Department inventory of beds" means the current list for each planning area maintained on a continuous basis by the Department of licensed hospital beds designated for NICU services and NICU beds with valid CON approval but not yet licensed or designated.

(f) "Existing NICU beds" means the total number of all of the following:

(i) licensed hospital beds designated for NICU services;

(ii) NICU beds with valid CON approval but not yet licensed or designated;

(ii) NICU beds under appeal from a final decision of the Department; and

(iii) proposed NICU beds that are part of an application for which a proposed decision has been issued, but is pending final Department decision.

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

(h) "Infant" means an individual up to 1 year of age.

(i) "Licensed site" means in the case of a single site hospital, the location of the facility authorized by license and listed on that licensee's certificate of licensure; or in the case of a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility as authorized by license and listed on that licensee's certificate of licensure.

(j) "Live birth" means a birth for which a birth certificate for a live birth has been prepared and filed pursuant to Section 333.2821(2) of the Michigan Compiled Laws.

(k) "Maternal referral service" means having a consultative and patient referral service staffed by a physician(s), on the active medical staff, that is board certified, or eligible to be board certified, in maternal/fetal medicine.

(l) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396w-5.

(m) "Neonatal intensive care services" or "NICU services" means the provision of any of the following services:

(i) constant nursing care and continuous cardiopulmonary and other support services for severely ill infants;

(ii) care for neonates weighing less than 1,500 grams at birth, and/or less than 32 weeks gestation;

(iii) ventilatory support beyond that needed for immediate ventilatory stabilization;

(iv) surgery and post-operative care during the neonatal period;

(v) pharmacologic stabilization of heart rate and blood pressure; or

(vi) total parenteral nutrition.

(n) "Neonatal intensive care unit" or "NICU" means a specially designed, equipped, and staffed unit of a hospital which is both capable of providing neonatal intensive care services and is composed of licensed hospital beds designated as NICU. This term does not include unlicensed SCN beds.

(o) "Neonatal transport system" means a specialized transfer program for neonates by means of an ambulance licensed pursuant to Part 209 of the Code, being Section 333.20901 et seq.

(p) "Neonate" means an individual up to 28 days of age.

(q) "Perinatal care network," means the providers and facilities within a planning area that provide basic, specialty, and sub-specialty obstetric, pediatric and neonatal intensive care services.

(r) "Planning area" means the groups of counties shown in Appendix B.

(s) "Planning year" means the most recent continuous 12 month period for which birth data is available from the Vital Records and Health Data Development Section.

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

(u) "Relocation of the designation of beds for NICU services" means a change within the same planning area in the licensed site at which existing licensed hospital beds are designated for NICU services.

(v) "Special care nursery services" or “SCN services” means provisions of the services identified in subsections (i) through (v) for infants with problems that are expected to resolve rapidly and who would not be anticipated to need subspecialty services on an urgent basis. Referral to a higher level of care should occur for all infants who need pediatric surgical or medical subspecialty intervention. Infants receiving transitional care or being treated for developmental maturation may have formerly been treated in a neonatal intensive care unit in the same hospital or another hospital. For purposes of these standards, SCN services are special newborn nursing services.

(i) Care for low birth weight infants weighing 1,500grams or more and/or greater than or equal to 32 weeks gestation;

(ii) enteral tube feedings;

(iii) cardio-respiratory monitoring to document maturity of respiratory control or treatment of apnea;

(iv) extended care following an admission to a neonatal intensive care unit for an infant not requiring ventilatory support; or

(v) provide mechanical ventilation or continuous positive airway pressure or both for a brief duration (not to exceed 24 hours combined).

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

Section 3. Bed need methodology

Sec. 3. (1) The number of NICU beds needed in a planning area shall be determined by the following formula:

(a) Determine, using data obtained from the Vital Records and Health Data Development Section, the total number of live births which occurred in the planning year at all hospitals geographically located within the planning area.

(b) Determine, using data obtained from the Vital Records and Health Data Development Section, the percent of live births in each planning area and the state that were less than 1,500 grams. The result is the very low birth weight rate for each planning area and the state, respectively.

(c) Divide the very low birth weight rate for each planning area by the statewide very low birth weight rate. The result is the very low birth weight rate adjustment factor for each planning area.

(d) Multiply the very low birth weight rate adjustment factor for each planning area by 0.0045. The result is the bed need formula for each planning area adjusted for the very low birth weight rate.

(e) Multiply the total number of live births determined in subsection (1)(a) by the bed need formula for the applicable planning area adjusted for the very low birth weight adjustment factor as determined in subsection (1)(d).

(2) The result of subsection (1) is the number of NICU beds needed in the planning area for the planning year.

Section 4. Requirements to initiate NICU services

Sec. 4. Initiation of NICU services means the establishment of a NICU at a licensed site that has not had in the previous 12 months a licensed and designated NICU or does not have a valid CON to initiate a NICU. The relocation of the designation of beds for NICU services meeting the applicable requirements of Section 6 shall not be considered as the initiation of NICU services/beds.

(1) An applicant proposing to initiate NICU services by designating hospital beds as NICU beds shall demonstrate each of the following:

(a)There is an unmet bed need of at least 15 NICU beds based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year as a result of application of the methodology set forth in Section 3.

(b) Approval of the proposed NICU will not result in a surplus of NICU beds in the planning area based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year resulting from application of the methodology set forth in Section 3.

(c) A unit of at least 15 beds will be developed and operated.

(d) For each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the licensed site at which the NICU is proposed had either: (i) 2,000 or more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles (surface travel) from the nearest licensed site that operates or has valid CON approval to operate NICU services.

Section 5. Requirements to REPLACE NICU services

Sec. 5. Replacement of NICU beds means new physical plant space being developed through new construction or newly acquired space (purchase, lease or donation), to house existing licensed and designated NICU beds.

(1) An applicant proposing replacement beds shall not be required to be in compliance with the needed NICU bed supply determined pursuant to Section 3 if an applicant demonstrates all of the following:

(a) the project proposes to replace an equal or lesser number of beds designated by an applicant for NICU services at the licensed site operated by the same applicant at which the proposed replacement beds are currently located; and

(b) the proposed licensed site is in the same planning area as the existing licensed site and in the area set forth in Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, in which replacement beds in a hospital are not subject to comparative review.

Section 6. Requirements for approval to relocate NICU beds

Sec. 6. An applicant proposing to relocate the designation for NICU services shall demonstrate compliance with all of the following:

(1) The applicant is the licensed site to which the relocation of the designation of beds for NICU services is proposed.

(2) The applicant shall provide a signed written agreement that provides for the proposed increase, and concomitant decrease, in the number of beds designated for NICU services at the 2 licensed sites involved in the proposed relocation. A copy of the agreement shall be provided in the application.

(3) The existing licensed site from which the designation of beds for NICU services proposed to be relocated is currently licensed and designated for NICU services.

(4) The proposed project does not result in an increase in the number of beds designated for NICU services in the planning area unless the applicable requirements of Section 4 or 5 have also been met.

(5) The proposed project does not result in an increase in the number of licensed hospital beds at the applicant licensed site unless the applicable requirements of the CON Review Standards for Hospital Beds have also been met.

(6) The proposed project does not result in the operation of a NICU of less than 15 beds at the existing licensed site from which the designation of beds for NICU services are proposed to be relocated.

(7) If the applicant licensed site does not currently provide NICU services, an applicant shall demonstrate both of the following:

(a) the proposed project involves the establishment of a NICU of at least 15 beds; and

(b) for each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the applicant licensed site had either: (i) 2,000 or more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles from the nearest licensed site that operates or has valid CON approval to operate NICU services/beds. If the applicant licensed site has not been in operation for at least 3 years and the obstetrical unit at the applicant licensed site was established as the result of the consolidation and closure of 2 or more obstetrical units, the combined number of live births from the obstetrical units that were closed and relocated to the applicant licensed site may be used to evaluate compliance with this requirement for those years when the applicant licensed site was not in operation.

(8) If the applicant licensed site does not currently provide NICU services or obstetrical services, an applicant shall demonstrate both of the following:

(a) the proposed project involves the establishment of a NICU of at least 15 beds; and

(b) the applicant has a valid CON to establish an obstetrical unit at the licensed site at which the NICU is proposed. The obstetrical unit to be established shall be the result of the relocation of an existing obstetrical unit that for each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the obstetrical unit to be relocated had either: (i) 2,000 or more live births, if the obstetrical unit to be relocated is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the obstetrical unit to be relocated is located in a rural or micropolitan statistical area county and is located more than 100 miles from the nearest licensed site that operates or has valid CON approval to operate NICU services.

(9) The project results in a decrease in the number of licensed hospital beds that are designated for NICU services at the licensed site at which beds are currently designated for NICU services. The

decrease in the number of beds designated for NICU services shall be equal to or greater than the number of beds designated for NICU services proposed to be increased at the applicant's licensed site pursuant to the agreement required by this subsection. This subsection requires a decrease in the number of licensed hospital beds that are designated for NICU services, but does not require a decrease in the number of licensed hospital beds.

(10) Beds approved pursuant to Section 7(2) shall not be relocated pursuant to this section, unless the proposed project involves the relocation of all beds designated for NICU services at the applicant's licensed site.

Section 7. Requirements for approval to expand NICU services

Sec. 7. (1) An applicant proposing to expand NICU services at a licensed site by designating additional hospital beds as NICU beds in a planning area shall demonstrate that the proposed increase will not result in a surplus of NICU beds based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year resulting from application of the methodology set forth in Section 3.

(2) An applicant may apply and be approved for NICU beds in excess of the number determined as needed for the planning year in accordance with Section 3 if an applicant can demonstrate that it provides NICU services to patients transferred from another licensed and designated NICU. The maximum number of NICU beds that may be approved pursuant to this subsection shall be determined in accordance with the following:

(a) An applicant shall document the average annual number of patient days provided to neonates or infants transferred from another licensed and designated NICU, for the 2 most recent years for which verifiable data are available to the Department.

(b) The average annual number of patient days determined in accordance with subsection (a) shall be divided by 365 (or 366 for a leap year). The result is the average daily census (ADC) for NICU services provided to patients transferred from another licensed and designated NICU.

(c) Apply the ADC determined in accordance with subsection (b) in the following formula: ADC + 2.06 $\sqrt{ADC}$. The result is the maximum number of beds that may be approved pursuant to this subsection up to 5 beds at each licensed site.

Section 8. Requirements for approval to acquire a NICU service

Sec. 8. Acquisition of a NICU means obtaining possession and control of existing licensed hospital beds designated for NICU services by contract, ownership, lease or other comparable arrangement.

(1) An applicant proposing to acquire a NICU shall not be required to be in compliance with the needed NICU bed supply determined pursuant to Section 3 for the planning area in which the NICU subject to the proposed acquisition is located, if the applicant demonstrates that all of the following are met:

(a) the acquisition will not result in an increase in the number of hospital beds, or hospital beds designated for NICU services, at the licensed site to be acquired;

(b) the licensed site does not change as a result of the acquisition, unless the applicant meets Section 6; and,

(c) the project does not involve the initiation, expansion or replacement of a covered clinical service, a covered capital expenditure for other than the proposed acquisition or a change in bed capacity at the applicant facility, unless the applicant meets other applicable sections.

Section 9. Requirements to initiate, acquire, or replace SCN services

Sec. 9. An applicant proposing SCN services shall demonstrate each of the following, as applicable, by verifiable documentation:

(1) All applicants shall demonstrate the following:
(a) A board certified neonatologist serving as the program director.
(b) The hospital has the following capabilities and personnel continuously available and on-site:
(i) the ability to provide mechanical ventilation and/or continuous positive airway pressure for up to 24 hours;
(ii) portable x-ray equipment and blood gas analyzer;
(iii) pediatric physicians and/or neonatal nurse practitioners; and
(iv) respiratory therapists, radiology technicians, laboratory technicians and specialized nurses with experience caring for premature infants.

(2) Initiation of SCN services means the establishment of an SCN at a licensed site that has not had in the previous 12 months a designated SCN or does not have a valid CON to initiate an SCN.
(a) In addition to the requirements of Section 9(1), an applicant proposing to initiate an SCN service shall have a written consulting agreement with a hospital which has an existing, operational NICU. The agreement must specify that the existing service shall, for the first two years of operation of the new service, provide the following services to the applicant hospital:
(i) receive and make recommendations on the proposed design of SCN and support areas that may be required;
(ii) provide staff training recommendations for all personnel associated with the new proposed service;
(iii) assist in developing appropriate protocols for the care and transfer, if necessary, of premature infants;
(iv) provide recommendations on staffing needs for the proposed service; and
(v) work with the medical staff and governing body to design and implement a process that will annually measure, evaluate, and report to the medical staff and governing body the clinical outcomes of the new service, including:
(A) mortality rates;
(B) morbidity rates including intraventricular hemorrhage (grade 3 and 4), retinopathy of prematurity (stage 3 and 4), chronic lung disease (oxygen dependency at 36 weeks gestation), necrotizing enterocolitis, pneumothorax, neonatal depression (apgar score of less than 5 at five minutes); and
(C) infection rates.
(b) SCN services shall be provided in unlicensed SCN beds located within the hospital obstetrical department or NICU service. Unlicensed SCN beds are not included in the NICU bed need.

(3) Replacement of SCN services means new physical plant space being developed through new construction or newly acquired space (purchase, lease or donation), to house an existing SCN service.
(a) In addition to the requirements of Section 9(1), an applicant proposing a replacement SCN service shall demonstrate all of the following:
(i) The proposed project is part of an application to replace the entire hospital.
(ii) The applicant currently operates the SCN service at the current licensed site.
(iii) The proposed licensed site is in the same planning area as the existing licensed site.

(4) Acquisition of an SCN service means obtaining possession and control of an existing SCN service by contract, ownership, lease or other comparable arrangement.
(a) In addition to the requirements of Section 9(1), an applicant proposing to acquire an SCN service shall demonstrate all of the following:
(i) The proposed project is part of an application to acquire the entire hospital.

(ii) The licensed site does not change as a result of the acquisition, unless the applicant meets subsection 3.

Section 10. Additional requirements for applications included in comparative reviews.

Sec. 10. (1) Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and reviewed comparatively with other applications in accordance with the CON rules.

(2) Each application in a comparative review group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code, being Section 333.22225(1) of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards. If the Department determines that one or more of the competing applications satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1), and which have the highest number of points when the results of subsection (2) are totaled. If 2 or more qualifying projects are determined to have an identical number of points, the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1), which are proposed by an applicant that operates a NICU at the time an application is submitted to the Department. If 2 or more qualifying projects are determined to have an identical number of points and each operates a NICU at the time an application is submitted to the Department, the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1), in the order in which the applications were received by the Department, based on the submission date and time, as determined by the Department when submitted.

(a) A qualifying project will have points awarded based on the geographic proximity to NICU services, both operating and CON approved but not yet operational, in accordance with the following schedule:

Proximity	Points Awarded
Less than 50 Miles to NICU service	0
Between 50-99 miles to NICU service	1
100+ Miles to NICU service	2

(b) A qualifying project will have points awarded based on the number of very low birth weight infants delivered at the applicant hospital or the number of very low birth weight infants admitted or refused admission due to the lack of an available bed to an applicant's NICU, and the number of very low birth weight infants delivered at another hospital subsequent to the transfer of an expectant mother from an applicant hospital to a hospital with a NICU. The total number of points to be awarded shall be the number of qualifying projects. The number of points to be awarded to each qualifying project shall be calculated as follows:

(i) Each qualifying project shall document, for the 2 most recent years for which verifiable data are available, the number of very low birth weight infants delivered at an applicant hospital, or admitted to an applicant's NICU, if an applicant operates a NICU, the number of very low birth weight infants delivered to expectant mothers transferred from an applicant's hospital to a hospital with a NICU, and the number of very low birth weight infants referred to an applicant's NICU who were refused admission due to the lack of an available NICU bed and were subsequently admitted to another NICU.

(ii) Total the number of very low birth weight births and admissions documented in subdivision (i) for all qualifying projects.

(iii) Calculate the fraction (rounded to 3 decimal points) of very low birth weight births and admissions that each qualifying project's volume represents of the total calculated in subdivision (ii).

(iv) For each qualifying project, multiply the applicable fraction determined in subdivision (iii) by the total possible number of points.

(v) Each qualifying project shall be awarded the applicable number of points calculated in subdivision (iv).

(c) An applicant shall have 1 point awarded if it can be demonstrated that on the date an application is submitted to the Department, the licensed site at which NICU services/beds are proposed has on its active medical staff a physician(s) board certified, or eligible to be certified, in maternal/fetal medicine.

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

Hospital Indigent Volume	Points Awarded
0 - <6%	0.2
6 - <11%	0.4
11 - <16%	0.6
16 - <21%	0.8
21 - <26%	1.0
26 - <31%	1.2
31 - <36%	1.4
36 - <41%	1.6
41 - <46%	1.8
46% +	2.0

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total charges expressed as a percentage as determined by the Hospital and Health Plan Reimbursement Division pursuant to Section 7 of the Medical Provider manual. The indigent volume data being used for rates in effect at the time the application is deemed submitted will be used by the Department in determining the number of points awarded to each qualifying project.

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

Section 11. Requirements for Medicaid participation

Sec. 11. An applicant for NICU services and SCN services shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

Section 12. Project delivery requirements and terms of approval

Sec. 12. An applicant shall agree that, if approved, the NICU and SCN services shall be delivered in compliance with the following terms of approval:

(1) Compliance with these standards.

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

(a) An applicant shall coordinate its services with other providers of obstetrical, perinatal, neonatal and pediatric care in its planning area, and other planning areas in the case of highly specialized services.

(b) An applicant shall develop and maintain a follow-up program for NICU graduates and other infants with complex problems. An applicant shall also develop linkages to a range of pediatric care for high-risk infants to ensure comprehensive and early intervention services.

(c) If an applicant operates a NICU that admits infants that are born at a hospital other than the applicant hospital, an applicant shall develop and maintain an outreach program that includes both case-finding and social support which is integrated into perinatal care networks, as appropriate.

(d) If an applicant operates a NICU that admits infants that are born at a hospital other than the applicant hospital, an applicant shall develop and maintain a neonatal transport system.

(e) An applicant shall coordinate and participate in professional education for perinatal and pediatric providers in the planning area.

(f) An applicant shall develop and implement a system for discharge planning.

(g) A board certified neonatologist shall serve as the director of neonatal services.

(h) An applicant shall make provisions for on-site physician consultation services in at least the following neonatal/pediatric specialties: cardiology, ophthalmology, surgery and neurosurgery.

(i) An applicant shall develop and maintain plans for the provision of highly specialized neonatal/pediatric services, such as cardiac surgery, cardiovascular surgery, neurology, hematology, orthopedics, urology, otolaryngology and genetics.

(j) An applicant shall develop and maintain plans for the provision of transferring infants discharged from its NICU to another hospital, as necessary for the care of an infant no longer requiring NICU services but unable to be discharged home.

(3) Compliance with the following applicable quality assurance standards for SCN services:

(a) An applicant shall coordinate its services with other providers of obstetrical, perinatal, neonatal and pediatric care in its planning area, and other planning areas in the case of highly specialized services.

(b) An applicant shall develop and implement a system for discharge planning.

(c) A board certified neonatologist shall serve as the SCN program director.

(d) The hospital continues to have the following capabilities and personnel continuously available and on-site:

(i) The ability to provide mechanical ventilation and/or continuous positive airway pressure for up to 24 hours;

(ii) portable x-ray equipment and blood gas analyzer;

(iii) pediatric physicians and/or neonatal nurse practitioners; and

(iv) respiratory therapists, radiology technicians, laboratory technicians and specialized nurses with experience caring for premature infants.

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

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

(b) The NICU and SCN services shall not deny NICU and SCN services to any individual based on ability to pay or source of payment.

(c) The NICU and SCN services shall provide NICU and SCN services to any individual based on clinical indications of need for the services.

(d) The NICU and SCN services shall maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

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

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

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

(i) The SCN services shall provide data for the percentage of transfers to a higher level of care, hours of life at the time of transfer to a higher level of care, admissions to the SCN at less than 32 weeks gestation, number of admissions requiring respiratory support greater than 24 hours in duration, number of admissions to SCN, and rates of morbidity including: intraventricular hemorrhage (grade 3 and 4), retinopathy of prematurity (stage 3 and 4), chronic lung disease (oxygen dependency at 36 weeks gestation), necrotizing enterocolitis, and pneumothorax.

(b) The NICU and SCN services shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.

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

Section 13. Department inventory of beds

Sec. 13. The Department shall maintain a listing of the Department inventory of beds for each planning area.

Section 14. Effect on prior CON review standards; comparative reviews

Sec. 14. (1) These CON review standards supercede and replace the CON Review Standards for Neonatal Intensive Care Services/Beds approved by the Commission on ~~June 10, 2010~~DECEMBER 12, 2013 and effective on ~~August 12, 2010~~MARCH 3, 2014.

(2) Projects reviewed under these standards shall be subject to comparative review except for:

(a) Replacement beds meeting the requirements of Section 22229(3) of the Code, being Section 333.22229(3) of the Michigan Compiled Laws;

(b) The designation of beds for NICU services being relocated pursuant to Section 6 of these standards; or

(c) Beds requested under Section 7(2).

(d) SCN services requested under Section 9.

APPENDIX A

~~CON REVIEW STANDARDS~~ FOR ~~NEONATAL INTENSIVE CARE SERVICES/BEDS~~

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

Allegan	HILLSDALE	MASON
Alpena	Houghton	Mecosta
Benzie	IONIA	Menominee
Branch	Isabella	~~Midland~~
Chippewa	Kalkaska	Missaukee
Delta	Keweenaw	St. Joseph
Dickinson	Leelanau	Shiawassee
Grand Traverse	Lenawee	Wexford
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	~~Ionia~~	MONTCALM~~Newaygo~~
Bay	Jackson	Muskegon
Berrien	Kalamazoo	Oakland
Calhoun	Kent	Ottawa
Cass	Lapeer	Saginaw
Clinton	Livingston	St. Clair
Eaton	Macomb	Van Buren
Genesee	MIDLAND	Washtenaw
Ingham	Monroe	Wayne

Source:

~~65~~ 75 F.R., p. ~~82238~~ 37245 (~~December 27~~JUNE 28, ~~2000~~2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

APPENDIX B

The planning areas for neonatal intensive care services/beds are the geographic boundaries of the group of counties as follows:

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

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR SURGICAL SERVICES

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

Section 1. Applicability

Sec. 1. These standards are requirements for the approval of the initiation, replacement, expansion, or acquisition of a surgical service provided in a surgical facility and the delivery of these services under Part 222 of the Code. Surgical services provided in a freestanding surgical outpatient facility, an ambulatory surgery center certified under title XVIII, or a surgical department of a hospital licensed under Part 215 of the Code and offering inpatient or outpatient surgical services are covered clinical services . The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. For purposes of these standards:

(a) "Ambulatory surgical center" or "ASC" means any distinct entity certified by Medicare as an ASC under the provisions of Title 42, Part 416 that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization.

(b) "Burn care" means surgical services provided to burn patients in a licensed hospital site that has been verified as meeting the "Guidelines for Development and Operation of Burn Centers" issued by the American Burn Association in March 1988, or equivalent standards for a burn center.

(c) "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.

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

(e) "Cystoscopy" means direct visual examination of the urinary tract with a cystoscope.

(f) "Cystoscopy case" means a single visit to an operating room during which one or more cystoscopic procedures are performed.

(g) “Dedicated endoscopy or cystoscopy operating room” means a room used exclusively for endoscopy or cystoscopy cases.

(h) "Department" means the Michigan Department of Community Health (MDCH).

(i) “Emergency Room” means a designated area in a licensed hospital and recognized by the Department as having met the staffing and equipment requirements for the treatment of emergency patients.

(j) "Endoscopy" means visual inspection of any portion of the body by means of an endoscope.

(k) "Endoscopy case" means a single visit to an operating room during which one or more endoscopic procedures are performed.

(l) "Existing surgical service" means a surgical facility that, on the date an application is submitted to the Department, is part of a licensed hospital site, a licensed freestanding surgical outpatient facility, or a certified ASC.

(m) "Freestanding surgical outpatient facility" or "FSOF" means a health facility licensed under Part 208 of the Code. It does not include a surgical outpatient facility owned and operated as a part of a licensed hospital site. A freestanding surgical outpatient facility is a health facility for purposes of Part 222 of the Code.

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

(o) "Hours of use" means the actual time in hours, and parts thereof, an operating room is used to provide surgical services. It is the time from when a patient enters an operating room until that same patient leaves that same room. It excludes any pre- or post-operative room set-up or clean-up preparations, or any time a patient spends in pre- or post-operative areas including a recovery room.

(p) "Licensed hospital site" means either:

(i) in the case of a single site hospital, the location of the hospital authorized by license and listed on that licensee's certificate of licensure or

(ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient site as authorized by licensure.

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

~~(r) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~

~~(s) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~

(~~t~~r) "Offer" means to perform surgical services.

(~~u~~s) "Operating room" or "OR" means a room in a surgical facility constructed and equipped to perform surgical cases and located on a sterile corridor. The term also includes a room constructed and equipped to perform surgical cases on a nonsterile corridor if the room is located in an FSOF or ASC that is used exclusively for endoscopy or cystoscopy cases. This term does not include procedure rooms.

(~~v~~t) "Operating suite," for purposes of these standards, means an area in a surgical facility that is dedicated to the provision of surgery. An operating suite includes operating rooms, pre- and post-operative patient areas, clean and soiled utility and linen areas, and other support areas associated with the provision of surgery.

(~~w~~u) "Outpatient surgery" means the provision of surgical services performed in a hospital, FSOF, or ASC, requiring anesthesia or a period of post-operative observation, or both, to patients whose admission to a hospital for an overnight stay is not anticipated as being medically necessary.

(~~x~~v) "Procedure room" means a room in a surgical facility constructed and equipped to perform surgical procedures and not located on a sterile corridor.

(~~y~~w) "Renovate an existing surgical service or one or more operating rooms" means a project that:

(i) involves the renovation, remodeling, or modernization of an operating suite of a hospital, FSOF, or ASC;

(ii) does not involve new construction;

(iii) does not involve a change in the physical location within the surgical facility at the same site; and

(iv) does not result in an increase in the number of operating rooms at an existing surgical facility.

Renovation of an existing surgical service or one or more operating rooms may involve a change in the number of square feet allocated to an operating suite. The renovation of an existing surgical service or one or more operating rooms shall not be considered the initiation, expansion, replacement, or acquisition of a surgical service or one or more operating rooms.

~~(z) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States Office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~

(~~aa~~x) "Sterile corridor" means an area of a surgical facility designated primarily for surgical cases and surgical support staff. Access to this corridor is controlled and the corridor is not used by the general public or personnel of the surgical facility whose primary work station is not in the operating suite(s) or whose primary work tasks do not require them to be in the operating suite(s) of a surgical facility. Examples of personnel who would normally use sterile corridors include physicians, surgeons, operating room nurses,

laboratory or radiology personnel, and central supply or housekeeping personnel. Other terms commonly used to represent "sterile" in describing access areas include "restricted," "controlled," "limited access," or "clean."

(~~bby~~) "Surgical case" means a single visit to an operating room during which one or more surgical procedures are performed.

(ii) "Surgical facility" means either:

(i) a licensed FSOF;

(ii) a certified ASC; or

(iii) a licensed hospital site authorized to provide inpatient or outpatient surgery.

(jj) "Surgical service" means performing surgery in a surgical facility.

(~~ccz~~) "Trauma care," for purposes of these standards, means surgical services provided to a trauma patient in a licensed hospital site that has been verified as meeting the standards of the American College of Surgeons for a Level I or II trauma center, or equivalent standards.

(~~dd~~aa) "Verifiable data" means surgical data (cases and/or hours) from the most recent Annual Survey or more recent data that can be validated by the Department.

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

Section 3. Inventory of operating rooms used to perform surgical services; surgical cases, or hours of use; and evaluating compliance with minimum volume requirements

Sec. 3. (1) The Department shall use the number of operating rooms and verifiable data pursuant to subsection (2) to determine the number of surgical cases, hours of use, or both, as applicable, pursuant to subsection (3) for purposes of evaluating compliance with the actual and proposed volume requirements set forth in the applicable sections of these standards. Compliance with CON minimum volume requirements established by these standards shall be determined based on the average number of surgical cases, hours of use, or both, per operating room of the surgical service as permitted by these standards.

(2) The number of operating rooms for each type of surgical facility shall be determined as follows:

(a) In a licensed hospital site, all operating rooms in which surgery is or will be performed excluding:

(i) A delivery room(s) if that room is located in an area of a licensed hospital site designated primarily for obstetrical services.

(ii) An operating room that is or will be used exclusively for endoscopy or cystoscopy cases.

(iii) An operating room in which a fixed lithotripter is or will be located and utilized. A mobile lithotripter shall not be considered as an operating room.

(iv) An operating room that is or will be used, though not exclusively, to provide surgical services to patients requiring burn care or trauma care, as those terms are defined in these standards. No more than 0.5 burn care and 0.5 trauma care operating rooms shall be excluded pursuant to this subdivision, and precludes the use of the room in subsection (2)(a)(v).

(v) An operating room that is or will be used exclusively to provide surgical services to patients requiring burn care or trauma care, as those terms are defined in these standards. No more than 1 burn care and 1 trauma care operating room shall be excluded pursuant to this subdivision, and precludes the use of the room in subsection (2)(a)(iv).

(vi) A hybrid ORCCL shall have 0.5 excluded for each room meeting the requirements of section of these standards. A surgical facility will not be limited to the number of hybrid ORCCLS within a single licensed facility.

(b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all rooms in which endoscopy or cystoscopy cases are or will be performed.

(c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all operating rooms in which surgery is or will be performed, excluding any operating rooms used exclusively for endoscopy or cystoscopy cases.

(3) The number of surgical cases, or hours of use, shall be determined as follows:

(a) In a licensed hospital site, all surgical cases, or hours of use, performed in operating rooms, including surgical cases, or hours of use, performed in an operating room identified in subsection (2)(a)(iv), but excluding the surgical cases, or hours of use, performed in operating rooms identified in subsection (2)(a)(i), (ii), and (iii).

(b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all endoscopy or cystoscopy cases, or hours of use, performed in the operating rooms identified in subsection (2)(b).

(c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all surgical cases, or hours of use, performed in the operating rooms identified in subsection (2)(c). Cases, or hours of use, performed in any operating room used exclusively for endoscopy or cystoscopy cases, shall be excluded.

Section 4. Requirements to initiate a surgical service

Sec. 4. To initiate a surgical service means to begin operation of a surgical facility at a site that has not offered surgical services within the 12-month period immediately preceding the date an application is submitted to the Department. An applicant proposing to initiate a surgical service shall demonstrate the following, as applicable to the proposed project.

(1) Each proposed operating room shall perform an average of at least 1,128 surgical cases per year per operating room in the second 12 months of operation.

(2) Subsection (1) shall not apply if the proposed project involves the initiation of a surgical service with 1 or 2 operating rooms at a licensed hospital site located in a rural or micropolitan statistical area county that does not offer surgical services as of the date an application is submitted to the Department.

(3) An applicant shall demonstrate that it meets the requirements of Section 10(2) for the number of surgical cases projected under subsection (1).

Section 5. Requirements to replace a surgical service

Sec. 5. To replace a surgical service or one or more operating rooms, means the development of new space (whether through new construction, purchase, lease or similar arrangement) to house one or more operating rooms operated by an applicant at the same site as the operating room(s) to be replaced. This also includes designating an OR as a dedicated endoscopy or cystoscopy OR. The term also includes relocating an existing surgical facility or one or more operating rooms to a new geographic location of an existing surgical facility or one or more operating rooms to a different location currently offering surgical services. The term does not include the renovation of an existing surgical service or one or more operating rooms. An applicant requesting to replace an existing surgical service shall demonstrate each of the following, as applicable to the proposed project.

(1) An applicant proposing to replace shall demonstrate:

(a) All existing operating rooms in the existing surgical facility have performed an average of at least:

(i) 1,042 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room for which verifiable data is available to the Department, or

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.), or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(b) All operating rooms, existing and replaced, are projected to perform an average of at least:

(i) 1,042 surgical cases per year per operating room in the second twelve months of operation, and annually thereafter, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in the second twelve months of operation, and annually thereafter, or

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.), or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(2) An applicant proposing to replace one or more operating rooms at a licensed hospital and is located in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent federal decennial census shall demonstrate each of the following:

(a) The applicant has three, four, or five ORs at the licensed hospital.

(b) All existing operating rooms have performed an average of at least:

(i) 839 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,200 hours of use per year per operating room for which verifiable data is available to the Department.

(c) All operating rooms, existing and replaced, are projected to perform an average of at least:

(i) 839 surgical cases per year per operating room in the second twelve months of operation, and annually thereafter, or

(ii) 1,200 hours of use per year per operating room in the second twelve months of operation, and annually thereafter.

(3) Subsections (1) and (2) shall not apply if the proposed project involves replacing one or more operating rooms at the same licensed hospital site if the surgical facility is located in a rural or micropolitan statistical area county and has one or two operating rooms.

(4) Subsections (1) and (2) shall not apply to those hospitals licensed under Part 215 of PA 368 of 1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs at the surgical service has not increased as of March 31, 2003, and the location does not change.

(5) An applicant proposing to designate an OR as a dedicated endoscopy or cystoscopy OR shall submit notification to the Department on a form provided by the Department. An applicant under this subsection shall not be required to comply with subsections (1) and (2).

(6) An applicant proposing to relocate an existing surgical service or one or more operating rooms shall demonstrate each of the following, as applicable:

(a) The proposed new site is within a 10-mile radius of the site at which an existing surgical service is located if an existing surgical service is located in a metropolitan statistical area county, or a 20-mile radius if an existing surgical service is located in a rural or micropolitan statistical area county.

(b) All existing operating rooms in the surgical facility from which one or more ORs are proposed to be relocated have performed an average of at least:

(i) 1,042 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room for which verifiable data is available to the Department, or,

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.), or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(c) All operating rooms, existing and relocated, are projected to perform an average of at least:

(i) 1,042 surgical cases per year per operating room in the second twelve months of operation or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in the second twelve months of operation, and annually thereafter, or

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.) or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(7) Subsection (6) shall not apply if the proposed project involves relocating one or two operating rooms within a 20-mile radius if the surgical facility is located in a rural or micropolitan statistical area county.

(8) An applicant proposing to relocate one or more operating rooms from one licensed hospital site to another licensed hospital site and is located in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent federal decennial census shall demonstrate each of the following:

(a) The applicant has three, four, or five ORs at the licensed hospital.

(b) All existing operating rooms have performed an average of at least:

(i) 839 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,200 hours of use per year per operating room for which verifiable data is available to the Department.

(c) All operating rooms, existing and relocated, are projected to perform an average of at least:

(i) 839 surgical cases per year per operating room in the second twelve months of operation or

(ii) 1,200 hours of use per year per operating room in the second twelve months of operation,.

(9) An applicant shall demonstrate that it meets the requirements of Section 10(2) for the number of surgical cases, or hours of use, projected under subsection (1), (2), (6), and (8).

Section 6**. Requirements to expand an existing surgical service**

Sec. 6. To expand a surgical service means the addition of one or more operating rooms at an existing surgical service. This term also includes the change from a dedicated endoscopy or cystoscopy OR to a non-dedicated OR. An applicant proposing to add one or more operating rooms at an existing surgical service shall demonstrate each of the following as applicable, to the proposed project.

(1) An applicant shall demonstrate the following:

(a) All existing operating rooms in the existing surgical facility have performed an average of at least:

(i) 1,216 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,313 hours of use in a facility that performs only outpatient surgery per year per operating room for which verifiable data is available to the Department, or

(iii) a licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,750 plus the outpatient hours divided by 1,313. (For example: Using 438 inpatient hours and 985 outpatient hours would equate to 438/1,750 + 985/1,313 = 0.25 + 0.75 = 1.00 OR), or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,750 plus the outpatient cases divided by 1,216. (For example: Using 438 inpatient hours and 912 outpatient cases would equate to 438/1,750 + 912/1,216 = 0.25 + 0.75 = 1.00 OR.)

(b) All proposed operating rooms are projected to perform an average of at least:

(i) 1,042 surgical cases per year per operating room in the second twelve months of operation, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in the second twelve months of operation, or

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in the second twelve months of operation, and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.), or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room in the second twelve months of operation, and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(2) An applicant proposing to add one or more operating rooms at a licensed hospital and is located in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent federal decennial census shall demonstrate each of the following:

(a) The applicant has two, three, or four ORs at the licensed hospital.

(b) All existing operating rooms have performed an average of at least:

(i) 979 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,400 hours of use per year per operating room for which verifiable data is available to the Department.

(c) All proposed operating rooms are projected to perform an average of at least:

(i) 839 surgical cases per year per operating room in the second twelve months of operation, or

(ii) 1,200 hours of use per year per operating room in the second twelve months of operation.

(3) Subsections (1) and (2) shall not apply if the proposed project involves adding a second operating room in a licensed hospital site located in a rural or micropolitan statistical area county that currently has only one operating room.

(4) An applicant shall demonstrate that it meets the requirements of Section 10(2) for the number of surgical cases, or hours of use, projected under subsections (1) and (2).

Section 7. Requirements to acquire an existing surgical service

Sec. 7. Acquisition of a surgical service means a project involving the issuance of a new license for a hospital or a freestanding surgical outpatient facility or a new certification as an ambulatory surgical center as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing surgical service. An applicant proposing to acquire an existing surgical service shall demonstrate each of the following, as applicable to the proposed project.

(1) An applicant agrees and assures to comply with all applicable project delivery requirements.

(2) For the first application proposing to acquire an existing surgical service, for which a final decision has not been issued, on or after January 27, 1996, the existing surgical service shall not be required to be in compliance with the applicable volume requirements set forth in these standards. The surgical service shall be operating at the applicable volume requirements in the second 12 months after the effective date of the acquisition.

(3) For any application proposing to acquire an existing surgical service except the first application, for which a final decision has not been issued, on or after January 27, 1996, the existing surgical service shall be required to be in compliance with the applicable volume requirements on the date the application is submitted to the Department.

(4) Subsection (3) shall not apply to those hospitals licensed under Part 215 of PA 368 of 1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs at the surgical service has not increased as of March 31, 2003, and the location does not change.

Section 8. Requirements for a Hybrid Operating Room/Cardiac Catheterization Laboratory (OR/CCL)

Sec. 8. A hybrid or/ccl means an operating room located on a sterile corridor and equipped with an angiography system permitting minimally invasive procedures of the heart and blood vessels with full anesthesia capabilities. An applicant proposing to add one or more hybrid OR/CCLS at an existing surgical service shall demonstrate each of the following:

(1) The applicant operates an open heart surgery service which is in full compliance with the current con review standards for open heart surgery services.

(2) If the hybrid OR/CCL(s) represents an increase in the number of licensed operating rooms at the facility, the applicant is in compliance with Section 6 of these standards.

(3) If the hybrid OR/CCL(s) represents conversion of an existing operating room(s), the applicant is in compliance with the provisions of Section 5, if applicable.

(4) The applicant meets the applicable requirements of the CON review standards for cardiac catheterization services.

(5) Each case performed in a hybrid OR/CCL shall be included either in the surgical volume or the therapeutic cardiac catheterization volume of the facility. No case shall be counted more than once.

Section 9. Requirements for Medicaid Participation

Sec. 9. 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 10. Project delivery requirements terms of approval for all applicants

Sec. 10. An applicant shall agree that, if approved, the surgical services shall be delivered in compliance with the following terms of approval:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(i) The designation of ORs as defined by the standards shall not be changed without prior notification to the Department.

(ii) Surgical facilities shall have established policies for the selection of patients and delineate procedures which may be performed in that particular facility.

(iii) Surgical facilities shall have provisions for handling all types of in-house emergencies, including cardiopulmonary resuscitation.

(iv) Surgical facilities performing outpatient surgery shall have policies which allow for hospitalization of patients when necessary. All surgeons who perform surgery within the facility shall have evidence of admitting privileges or of written arrangements with other physicians for patient admissions at a local hospital. The surgical facility shall have an established procedure, including a transfer agreement that provides for the immediate transfer of a patient requiring emergency care beyond the capabilities of the surgical facility to a hospital that is capable of providing the necessary inpatient services and is located within 30 minutes of the surgical facility. If no hospital is located within 30 minutes of the surgical facility, an applicant shall have a transfer agreement with the nearest hospital having such capability.

(v) An applicant shall have written policies and procedures regarding the administration of a surgical facility.

(vi) An applicant shall have written position descriptions which include minimum education, licensing, or certification requirements for all personnel employed at the surgical facility.

(vii) An applicant shall have a process for credentialing individuals authorized to perform surgery or provide anesthesia services at a surgical facility. An applicant's credentialing process shall insure that the selection and appointment of individuals to the staff of a surgical facility does not discriminate on the basis of licensure, registration, or professional education as doctors of medicine, osteopathic medicine and surgery, podiatric medicine and surgery, or dentistry.

(viii) An applicant shall provide laboratory, diagnostic imaging, pathology and pharmacy (including biologicals) services, either on-site or through contractual arrangements.

(ix) An applicant shall have written policies and procedures for advising patients of their rights.

(x) An applicant shall develop and maintain a system for the collection, storage, and use of patient records.

(xi) Surgical facilities shall have separate patient recovery and non-patient waiting areas.

(xii) Surgical facilities shall provide a functionally safe and sanitary environment for patients, personnel, and the public. Each facility shall incorporate a safety management program to maintain a physical environment free of hazards and to reduce the risk of human injury.

(B) For purposes of evaluating subsection (A), the Department shall consider it prima facie evidence as to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint Commission on the Accreditation of Healthcare Organizations, the American Osteopathic Hospital Association, or the Accreditation Association for Ambulatory Health Care, or certified by Medicare as an ambulatory surgical center.

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

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

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

(b) not deny surgical services to any individual based on ability to pay or source of payment;

(c) provide surgical services to any individual based on the clinical indications of need for the service.

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

(e) An applicant shall participate in Medicaid or in Medicaid managed care products at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter or attest that the applicant has been unable to contract with Medicaid managed care products at current Medicaid rates.

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

(a) Existing operating rooms shall perform an average of at least:

(i) 1,042 surgical cases per year per operating room verifiable by the Department, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room verifiable by the Department, or

(iii) Be in compliance using the applicable weighted averages under Section 5.

(b) Existing operating rooms, located in a rural or micropolitan county, or within a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent Federal decennial census in a surgical service that has three, four, or five OR'S shall perform an average of at least:

(i) 839 surgical cases per year per operating room verifiable by the Department or

(ii) 1,200 hours of use per year per operating room verifiable by the Department.

(c) The applicant shall participate in a data collection System established and administered by the Department. The data may include, but is not limited to, hours of use of operating rooms, 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 payer sources. An applicant shall provide the required data on a separate basis for each licensed or certified 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.

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

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

Section 11. Documentation of projections

Sec. 11. (1) An applicant required to project volumes of service shall specify how the volume projections were developed and shall include only those surgical cases performed in an OR.

(a) The applicant shall include a description of the data source(s) used as well as an assessment of the accuracy of these data used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

(b) The Department shall subtract any previous commitment, pursuant to subsection 2(d).

(2) If a projected number of surgical cases, or hours of use, under subsection (1) includes surgical cases, or hours of use, performed at another existing surgical facility(s), an applicant shall demonstrate, with documentation satisfactory to the Department, that the utilization of the existing surgical facility(s) is in compliance with the volume requirements applicable to that facility, and will continue to be in compliance with the volume requirements (cases and/or hours) applicable to that facility subsequent to the initiation, expansion, or replacement of the surgical services proposed by an applicant. In demonstrating compliance with this subsection, an applicant shall provide each of the following:

(a) The name of each physician that performed surgical cases to be transferred to the applicant surgical facility.

(b) The number of surgical cases each physician, identified in subdivision (a), performed during the most recent 12-month period for which verifiable data is available.

(c) The location(s) at which the surgical cases to be transferred were performed, including evidence that the existing location and the proposed location are within 20 miles of each other.

(d) A written commitment from each physician, identified in subdivision (a), that he or she will perform at least the volume of surgical cases to be transferred to the applicant surgical facility for no less than 3 years subsequent to the initiation, expansion, or replacement of the surgical service proposed by an applicant.

(e) The number of surgical cases performed, at the existing surgical facility from which surgical cases will be transferred, during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable annual survey data is available.

(3) An applicant, other than an applicant proposing to initiate a surgical service, may utilize hours of use in documenting compliance with the applicable sections of these standards, if an applicant provides documentation, satisfactory to the Department, from the surgical facility from which the hours of use are being transferred.

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

Sec. 12. Proposed projects reviewed under these standards shall not be subject to comparative review. These CON review standards supercede and replace the CON Review Standards for Surgical Facilities approved by the CON Commission on ~~April 30, 2008~~DECEMBER 15, 2011 and effective on ~~June 20, 2008~~FEBRUARY 27, 2012.

APPENDIX A

~~CON REVIEW STANDARDS~~ ~~FOR SURGICAL SERVICES~~

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

Allegan	HILLSDALE	MASON
Alpena	Houghton	Mecosta
Benzie	IONIA	Menominee
Branch	Isabella	~~Midland~~
Chippewa	Kalkaska	Missaukee
Delta	Keweenaw	St. Joseph
Dickinson	Leelanau	Shiawassee
Grand Traverse	Lenawee	Wexford
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	~~Ionia~~	MONTCALM~~Newaygo~~
Bay	Jackson	Muskegon
Berrien	Kalamazoo	Oakland
Calhoun	Kent	Ottawa
Cass	Lapeer	Saginaw
Clinton	Livingston	St. Clair
Eaton	Macomb	Van Buren
Genesee	MIDLAND	Washtenaw
Ingham	Monroe Wayne	

Source:

~~65~~ 75 F.R., p. ~~82238~~ 37245 (~~December 27~~JUNE 28, ~~2000~~2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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 (MDCH).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) An applicant proposing to initiate a UESWL service shall demonstrate each of the following:
(a) The capability to provide complicated stone disease treatment on-site.
(b) At least 1,000 procedures are projected pursuant to the methodology set forth in Section 10(1).
(c) The proposed UESWL service shall be provided at a site that provides, or will provide, each of the following:
(i) On-call availability of an anesthesiologist and a surgeon.
(ii) On-site Advanced Cardiac Life Support (ACLS)-certified personnel and nursing personnel.
(iii) On-site 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) On-site 23-hour holding unit.

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

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

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

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

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

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

(5) An applicant proposing to relocate its existing UESWL service and its unit(s) 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 has been in operation for at least 36 months as of the date an application is submitted to the Department.
(c) The site to which the UESWL service will be relocated meets the requirements of Section 3(1)(c).
(d) 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.
(e) The UESWL service and its unit(s) to be relocated 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.
(f) 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 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 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 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.
(d) Each existing UESWL unit(s) at the service from which a unit is to be relocated 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 applicant proposing to acquire an existing fixed or mobile UESWL service and its unit(s) shall demonstrate that a proposed project meets all of the following:
(a) For an application for the proposed first acquisition of an existing fixed or mobile 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) For any application for proposed acquisition of an existing fixed or mobile UESWL service, except the first application approved pursuant to subsection (a), for which a final decision has not been issued after MAY 2, 1998, an applicant shall be required to demonstrate that the UESWL service and its unit(s) to be acquired performed an average of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data.

(2) 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.

Section 7. Additional requirements for approval for mobile UESWL services

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 8. Requirements for Medicaid participation

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

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

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

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

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

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

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

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

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

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

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

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

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

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

(ii) Provide all UESWL services to any individual based on clinical indications of need for the services, and

(iii) Maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 10. Methodology for projecting UESWL procedures

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

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

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

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

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

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

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

Section 11. Requirements for MIDB data commitments

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

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

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

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

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

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

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

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

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

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

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

Section 12. Effect on prior planning policies; comparative reviews

Sec. 12. (1) These CON review standards supersede and replace the CON review standards for urinary extracorporeal shock wave lithotripsy (UESWL) services approved by the CON Commission on ~~December 11, 2007~~MARCH 18, 2014 and effective on ~~February 25, 2008~~JUNE 2, 2014.

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

APPENDIX A

Factor For Calculating Projected UESWL Procedures

(1) Until changed by the Department, the factor to be used in Section 10(1)(b) used for calculating the projected number of UESWL procedures shall be 1.09.

(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. "Metropolitan statistical area counties" will be assigned "urban" status, and "micropolitan statistical area" and "rural" counties will be assigned "rural" status.

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

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

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

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

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

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

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

APPENDIX B

Counties assigned to each region are as follows:

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

APPENDIX C

~~CON REVIEW STANDARDS~~
~~FOR UESWL SERVICES~~

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

Allegan	HILLSDALE	MASON
Alpena	Houghton	Mecosta
Benzie	IONIA	Menominee
Branch	Isabella	~~Midland~~
Chippewa	Kalkaska	Missaukee
Delta	Keweenaw	St. Joseph
Dickinson	Leelanau	Shiawassee
Grand Traverse	Lenawee	Wexford
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	~~Ionia~~	MONTCALM~~Newaygo~~
Bay	Jackson	Muskegon
Berrien	Kalamazoo	Oakland
Calhoun	Kent	Ottawa
Cass	Lapeer	Saginaw
Clinton	Livingston	St. Clair
Eaton	Macomb	Van Buren
Genesee	MIDLAND	Washtenaw
Ingham	Monroe	Wayne

Source:

~~65~~ 75 F.R., p. ~~82238~~ 37245 (~~December 27~~JUNE 28, ~~2000~~2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

APPENDIX D

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

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

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

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

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Nursing Home and Hospital Long-Term-Care Unit (HLTCU) Beds
CON Review Standards
September 25, 2014

I am Pat Anderson with the Health Care Association of Michigan. HCAM represents both nursing homes and hospital long-term care units. HCAM would like to support the proposed changes to these standards and again thank the workgroup which included the department staff and interested stakeholders for their diligence on proposing these revisions to the standards.

HCAM does have one concern with the newly added proposed language defining "Proposed Licensed Site" which is lines 127-131. While HCAM wholly supports including this definition in the standards, the 250 yard limitation is too narrow. This new definition does address a workgroup issue that had not been resolved at that level prior to coming before the Commission. The proposed language reads:

> "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 the licensee's certificate of licensure.

HCAM proposes that "250 yards" be changed to "replacement zone" which provides for a three-mile radius as defined in these standards on line 151. Some of the reasons for needing to change a location are: local ordinance changes, wetlands, unsuitable soil to hold structure, environmental contamination and purchase price is unreasonable. All of these reasons can cause an applicant to seek a new location which can only be resolved at a distance greater than 250 yards. In fact, many nursing facility construction projects need between 6-8 acres to have adequate space to meet their proposed construction.

The flexibility that this definition allows is greatly hindered by the 250 yards restriction on the movement of the location. If the replacement zone three mile radius is used it should be adequate to address problems with the site and still ensure that services are provided to the original population it was intended to serve.

Thank you for considering HCAM's request to adjust the definition of "Proposed Licensed Site" from 250 yards to replacement zone.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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 ~~and delivery of nursing homes and HLTCU services~~ 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 ~~. A nursing home~~ 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 ~~are~~ IS A covered health ~~facilities~~ facilitY ~~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.

(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. For planning areas with an ADC of less than 100, the ADC adjustment factor is 0.90 and for planning areas with an ADC of 100 or more, the ADC adjustment factor is 0.95.

(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 Community Health Annual Survey of Long-Term-Care Facilities or other comparable MDCH 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 et seq. 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~~'s~~ OF LICENSING AND REGULATORY AFFAIRS~~'s~~(LARA), Bureau of Health ~~Systems~~CARE SERVICES.

(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 Community Health (MDCH).

(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.

(l) "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 Section 14.

(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~~r-6~~ TO 1396G and1396~~r-8~~l to ~~1396v~~1396U.

~~(r) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix C.~~

~~(s) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix C.~~

(~~t~~r) "New design model" means a nursing home/HLTCU built in accordance with specified design requirements as identified in the applicable sections.

(~~u~~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.

(~~v~~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.

(~~w~~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 calculated using verifiable data from ~~either (i)~~ the actual number of patient days of care for 12 continuous months of data from the ~~MDCH~~ CON Annual Survey ~~of Long-Term-Care Facilities~~ or other comparable MDCH survey instrument~~ or (ii) the actual number of patient days of care for 4 continuous quarters of data as reported to the Department for purposes of compiling the "Staffing/Bed Utilization Ratios Report," whichever is the most recent available data~~.

(~~x~~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.

(~~y~~w) "Planning year" means 1990 or the year in the future, at least three (3) years but no more than seven (7) years, ~~established by the CON Commission~~ 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, data are available.

(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.

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

(~~aa~~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 area.

(~~bb~~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.

(~~cc~~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, donation, etc.) within the replacement zone.

(~~dd~~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 licensed site.

(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.

~~(ee) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix C.~~

~~(ff~~cc) ~~"Staffing/Bed Utilization Ratios Report" means the report issued by the Department on a quarterly basis.~~

(~~gg~~cc) "Use rate" means the number of nursing home and hospital long-term-care unit days of care per 1,000 population during a one-year period.

(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) age 75 - 84 years, and (iv) age 85 and older.

(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 for each corresponding age cohort, established in accord with subsection (1)(b), are set forth in Appendix ~~A~~B.

(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 established in Appendix ~~A~~B.

(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) The following shall be known as the ADC adjustment factor. (i) If the ADC determined in subsection (d) is less than 100, divide the ADC by 0.90. (ii) If the ADC determined in subsection (d) is 100 or greater, divide the ADC by 0.95.

(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 ~~shown in Appendix B and incorporated as part of these standards~~ 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 ~~the~~ PREVIOUS bed need numbers ~~shown in Appendix B~~ and shall be ~~included as an amended appendix to these standards~~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:

(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 homes/HLTCUs	All Michigan nursing homes/HLTCUs under 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 homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or 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) ~~Outstanding~~ DELINQUENT debt obligation to the State of Michigan ~~for~~ 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 ~~Systems~~ CARE SERVICES within LARA.~~the Department~~. Code deficiencies include any unresolved deficiencies still outstanding with ~~the Department~~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 ~~set forth in Appendix B~~, unless one of the following is met:

(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 ~~set forth in Appendix B~~, 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 exception to the number of beds may be approved, if the applicant facility has experienced an average occupancy rate of 97% for ~~12 quarters~~THREE YEARS based on the ~~Department's "Staffing/Bed Utilization Ratios Report."~~CON ANNUAL SURVEY. The number of beds that may be approved in excess of the bed need for each planning area ~~identified in Appendix B~~ 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 ~~B~~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.

(iii) An applicant may request and be approved for up to a maximum of 20 beds if the following requirements are met:

(A) 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 ~~2000~~ 2010 U.S. Census figures as set forth in Appendix ~~D~~E.

(B) The applicant facility has experienced an average occupancy rate of 92% for the most recent ~~24 months~~TWO YEARS based on the ~~Department's "Staffing/Bed Utilization Ratios Report."~~CON ANNUAL SURVEY.

(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 homes/HLTCUs	All Michigan nursing homes/HLTCUs under 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 homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or 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) ~~Outstanding~~ DELINQUENT debt obligation to the State of Michigan INCLUDING, BUT NOT LIMITED TO, ~~for~~ 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 authorized by law.

(c) The proposed project shall include at least 80% single occupancy resident rooms with an adjoining ~~bathroom~~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 ~~set forth in Appendix B~~, 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 ~~Systems~~ CARE SERVICES within ~~the Department~~LARA. Code deficiencies include any unresolved deficiencies still outstanding with ~~the Department~~LARA.

~~**Section 7. Requirements for approval to relocate existing nursing home/HLTCU beds**~~

~~Sec. 7. (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 set forth in Appendix B, if the applicant demonstrates all of the following:~~

~~(a) An existing nursing home may relocate no more than 50% of its beds to another existing nursing home, and an existing HLTCU may relocate all or a portion of its beds to another existing nursing home/HLTCU.~~

~~(b) The nursing home/HLTCU from which the beds are being relocated and the nursing home/HLTCU receiving the beds shall not require any ownership relationship.~~

~~(c) The nursing home/HLTCU from which the beds are being relocated and the nursing home/HLTCU receiving the beds must be located in the same planning area.~~

~~(d) The nursing home/HLTCU from which the beds are being relocated has not relocated any beds within the last seven (7) years.~~

~~(e) The relocated beds shall be licensed to the receiving nursing home/HLTCU and will be counted in the inventory for the applicable planning area.~~

~~(f) 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.~~

~~(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 set forth in Appendix B, if the applicant demonstrates 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 homes/HLTCUs~~	~~All Michigan nursing homes/HLTCUs under 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 homes/HLTCUs and out of state nursing homes/HLTCUs~~	~~All Michigan and out of state nursing homes/HLTCUs under common ownership or 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) Outstanding debt obligation to the State of Michigan for Quality Assurance Assessment Program (QAAP) 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 Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department.~~

Section ~~8~~7. Requirements for approval to replace beds

Sec. ~~8~~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 ~~set forth in Appendix B~~ AND~~if~~ ~~the applicant demonstrates~~ 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 homes/HLTCUs	All Michigan nursing homes/HLTCUs under 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 homes/HLTCUS and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or 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) ~~Outstanding~~ DELINQUENT debt obligation to the State of Michigan INCLUDING, BUT NOT LIMITED TO, ~~for~~ 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 ~~Systems~~ CARE SERVICES within ~~the Department~~LARA. Code deficiencies include any unresolved deficiencies still outstanding with ~~the Department~~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 homes/HLTCUs	All Michigan nursing homes/HLTCUs under 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 homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or 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) ~~Outstanding~~ DELINQUENT debt obligation to the State of Michigan INCLUDING, BUT NOT LIMITED TO, ~~for~~ 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 ~~set forth in Appendix B~~.

(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 ~~Systems~~ CARE SERVICES within ~~the Department~~LARA. Code deficiencies include any unresolved deficiencies still outstanding with ~~the Department~~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 ~~set forth in Appendix B~~ AND~~if the applicant demonstrates~~ 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.

(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 ~~bathroom~~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~~, and not within a three mile radius of a licensed nursing home that has been newly constructed, or replaced (including approved projects) within five calendar years prior to the date of the application~~,

(~~i~~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

(~~ii~~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.

(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 ~~Systems~~ CARE SERVICES within ~~the Department~~LARA. Code deficiencies include any unresolved deficiencies still outstanding with ~~the Department~~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~~AND ~~the applicant demonstrates~~ all of the following REQUIREMENTS ARE MET:

~~(a) An existing nursing home may relocate no more than 50% of its beds to another existing nursing home, and an existing HLTCU may relocate all or a portion of its beds to another existing nursing home/HLTCU.~~

(~~b~~a) THERE SHALL NOT BE ANY OWNERSHIP RELATIONSHIP REQUIREMENTS BETWEEN ~~T~~the nursing home/HLTCU from which the beds are being relocated and the nursing home/HLTCU receiving the beds ~~shall not require any ownership relationship~~.

(~~c~~b) THE RELOCATED BEDS SHALL BE PLACED ~~The nursing home/HLTCU from which the beds are being relocated and the nursing home/HLTCU receiving the beds must be located~~ in the same planning area.

~~(d) The nursing home/HLTCU from which the beds are being relocated has not relocated any beds within the last seven (7) years.~~

(~~e~~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.

(~~f~~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.

(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~~AND ~~the applicant demonstrates~~ 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 homes/HLTCUs	All Michigan nursing homes/HLTCUs under 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 homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or 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) ~~Outstanding~~DELINQUENT debt obligation to the State of Michigan INCLUDING, BUT NOT LIMITED TO, ~~for~~ 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 ~~Systems~~CARE SERVICES within ~~the Department~~LARA. Code deficiencies include any unresolved deficiencies still outstanding with ~~the Department~~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:

(1) An applicant proposing to acquire an existing nursing home/HLTCU shall not be required to be in compliance with the needed nursing home bed supply ~~set forth in Appendix B~~ for the planning area in which the nursing home or HLTCU is located ~~if~~ AND ~~the applicant demonstrates~~ 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 homes/HLTCUs	All Michigan nursing homes/HLTCUs under 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 homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or 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) ~~Outstanding~~ DELINQUENT debt obligation to the state of Michigan INCLUDING, BUT NOT LIMITED TO, ~~for~~ 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 ~~Systems~~ CARE SERVICES within ~~the Department~~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 ~~Systems~~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).

(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 homes/HLTCUs	All Michigan nursing homes/HLTCUs under 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 homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or 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) ~~Outstanding~~ DELINQUENT debt obligation to the State of Michigan INCLUDING, BUT NOT LIMITED TO, ~~for~~ 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 ~~Systems~~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).

(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 ~~Systems~~ CARE SERVICES within ~~the Department~~LARA. Code deficiencies include any unresolved deficiencies still outstanding with ~~the Department~~LARA.

(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 ~~set forth in Appendix B~~ for the planning area in which the nursing home/HLTCU is located, ~~if~~ AND ~~the applicant demonstrates~~ 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 ~~Systems~~ CARE SERVICES within ~~the Department~~LARA. Code deficiencies include any unresolved deficiencies still outstanding with ~~the Department~~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 (calculated using total patient days for all existing and proposed beds at the facility)	Points Awarded	
	~~Current~~ EXISTING	Proposed
~~20~~ 50 – ~~59~~69%	~~6~~4	3
~~60~~ 70 – 100%	~~10~~8	~~5~~7

(b) A qualifying project will be awarded 10 points ~~as follows:~~

~~(i) For an existing nursing home/HLTCU, nine (9) points if 100%, six (6) points if 75%, and four (4) points if 50% of the licensed nursing home beds are Medicaid certified for the most recent 12 months of operations.~~

~~(ii) For a new nursing home/HLTCU, seven (7) points if 100%, four (4) points if 75%, and two (2) points if 50% of the proposed beds will be Medicaid certified by the second 12 months of operation following project completion~~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 be awarded points based on the most recent 12 months of participation level in the Medicare program for an existing nursing home/HLTCU and the proposed participation level for a new nursing home/HLTCU.~~

~~Participation Level~~	~~Points Awarded~~
~~Medicare certification of at least one (1) bed but less than 100%~~	~~1~~
~~Medicare certification of 100% of all existing and proposed beds~~	~~3~~

~~(4)~~ A qualifying project will have 15 points deducted if the applicant has any of the following at the time the application is submitted:

(a) ~~is currently a special focus nursing home/HLTCU as identified by the Centers for Medicare and Medicaid Services (CMS):~~

~~(b)~~ has been a special focus nursing home/HLTCU within the last three (3) years;

(~~c~~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);

(~~d~~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;

(~~e~~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

(~~f~~e) has any ~~outstanding~~ DELINQUENT debt obligation to the state of Michigan INCLUDING, BUT NOT LIMITED TO, ~~for~~ quality assurance assessment program (QAAP), civil monetary penalties (CMP), Medicaid level of care determination (LOCD), or preadmission screening and annual resident review (PASARR).

(~~5~~4) A qualifying project will be awarded ~~10~~ THREE (3) points if the applicant provides documentation that it participates or ~~five (5) points~~ 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.

(~~6~~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

(~~7~~6) ~~A qualifying project will be awarded five (5) points if the existing or proposed nursing home/HLTCU is fully equipped with sprinklers.~~

~~(8)~~ A qualifying project will be awarded ~~five~~ FOUR (~~5~~4) points if the ENTIRE existing ~~or~~ 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.

(~~9~~7) A qualifying project will be awarded SIX (6) OR FOUR (4) points based on ~~the proposed project as follows~~ONLY ONE OF THE FOLLOWING:

(a) SIX (6) POINTS IF THE PROPOSED PROJECT HAS 100% ~~private~~ rooms with DEDICATED TOILET ROOM CONTAINING A sink, WATER CLOSET, and ~~shower~~ 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 ~~shower~~BATHING FACILITY.

~~Facility Design~~	~~Points Awarded~~
~~100% private rooms with adjoining sink, toilet, and shower~~	~~10~~
~~100% private rooms with dedicated and shared adjoining toilet, sink and shower~~	~~5~~
~~80% private rooms with dedicated sink, shared adjoining toilet and sink, and central showers with adjoining space for drying and dressing in visual privacy~~	~~3~~

(~~10~~8) A qualifying project will be awarded 10 points if it results in a nursing home/HLTCU with 150 or fewer beds IN TOTAL.

~~(11) A qualifying project will be awarded five (5) points if the applicant provides its audited financial statements.~~

(~~12~~9) A qualifying project will be awarded five (5) points if the proposed beds will be housed in new construction.

(~~13~~10) A qualifying project will be awarded 10 points if the ENTIRE existing ~~AND PROPOSED~~ nursing home/HLTCU AND ITS PROPOSED PROJECT ~~eliminates all of its 3- and 4-bed wards~~WILL HAVE NO MORE THAN DOUBLE OCCUPANCY ROOMS AT COMPLETION OF THE PROJECT.

(~~14~~11) A qualifying project will be awarded ~~5~~ TWO (2) points if the existing or proposed nursing home/HLTCU is on or readily accessible to an existing or proposed public transportation route.

(~~15~~12) A qualifying project will be awarded ~~no more than four (4)~~ points for technological innovation as follows:

~~Technology Feature~~INNOVATIONS	Points Awarded
THE PROPOSED PROJECT WILL HAVE wireless nurse call/paging system including wireless devices carried by	1

direct care staff~~Electronic health record and computer point-of-service entry capability (including wireless tablets)~~	
WIRELESS INTERNET WITH RESIDENT ACCESS TO RELATED EQUIPMENT/DEVICE IN ENTIRE FACILITY~~Wireless nurse call/paging system including wireless devices carried by direct care staff~~	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~~Wireless internet in total existing and proposed facility~~	~~1~~4
~~Computer stations or internet cafes for resident use~~	~~1~~
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

(~~16~~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 400 POUNDS. THE BARIATRIC PATIENT ROOMS SHALL HAVE A LARGER ROOM AND BATHROOM ENTRANCE WIDTH 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.

(~~17~~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 (~~15~~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 ~~for all applicants~~

Sec. 11. ~~(1)~~ An applicant shall agree that, if approved, the ~~project~~ NURSING HOME/HLTCU SERVICES shall be delivered in compliance with the following terms of ~~CON~~ approval:

(~~a~~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-COMPLIANCE.

(~~b~~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 Community Health [subsection (iii) is applicable only to Section 10(2)(a)]. In 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.

(~~c~~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.

~~(d) Compliance with applicable operating standards.~~

~~(e) Compliance with the following quality assurance standards:~~

(~~i~~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.

(~~ii~~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:

(~~iii~~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 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.

(iv) The applicant shall provide the Department with ~~a~~ TIMELY notice ~~stating the date the beds are placed in operation and such notice shall be submitted to the Department~~ OF THE PROPOSED PROJECT IMPLEMENTATION consistent with applicable statute and promulgated rules.

(~~2~~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.

(~~3~~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. Health Service Areas**~~

~~Sec. 14. Counties assigned to each of the HSAs are as follows:~~

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

~~Delta~~ ~~Keweenaw~~ ~~Ontonagon~~
~~Dickinson~~ ~~Luce~~ ~~Schoolcraft~~

Section 15. Effect on prior CON review standards, comparative reviews

Sec. 15. (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 ~~April 30, 2008~~DECEMBER 15, 2010 and effective on ~~June 20, 2008~~MARCH 11, 2011.

(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 a rural county;

(b) replacement of an existing nursing home/HLTCU in a micropolitan or metropolitan statistical area county that is within two miles of the existing nursing home/HLTCU;

(c) relocation of existing nursing home/HLTCU beds; or

(d) an increase in beds pursuant to Section 6(1)(d)(ii) or (iii).

(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.

APPENDIX A

Counties assigned to each of the HSAs are as follows:

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

APPENDIX ~~A~~B

CON REVIEW STANDARDS
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 ~~March~~ AUGUST ~~1~~1, ~~2011~~2013, and until otherwise changed by the Commission, is as follows.

(i) Age 0 - 64: ~~208~~ 200 days of care

(ii) Age 65 - 74: ~~2,791~~ 2,638 days of care

(iii) Age 75 - 84: ~~10,047~~9379 days of care

(iv) Age 85 +: ~~36,758~~34,009 days of care

APPENDIX ~~B~~C

CON REVIEW STANDARDS FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT BEDS

The ~~bed need numbers~~ADC ADJUST FACTOR, for purposes of these standards, effective ~~TBD~~AUGUST 1, 2013, and until otherwise changed by the Commission, are as follows:

Planning Area	~~Bed Need~~	ADC Adjustment Factor
Alcona	~~115~~	0.~~95~~90
Alger	~~65~~	0.90
Allegan	~~500~~	0.95
Alpena	~~187~~	0.95
Antrim	~~168~~	0.95
Arenac	~~100~~	0.~~95~~90
Baraga	~~58~~	0.90
Barry	~~275~~	0.95
Bay	~~603~~	0.95
Benzie	~~124~~	0.95
Berrien	~~884~~	0.95
Branch	~~224~~	0.95
Calhoun	~~675~~	0.95
Cass	~~273~~	0.95
Charlevoix	~~159~~	0.95
Cheboygan	~~188~~	0.95
Chippewa	~~202~~	0.95
Clare	~~185~~	0.95
Clinton	~~319~~	0.95
Crawford	~~95~~	0.90
Delta	~~245~~	0.95
Dickinson	~~190~~	0.95
Eaton	~~491~~	0.95
Emmet	~~201~~	0.95
Genesee	~~1,880~~	0.95
Gladwin	~~184~~	0.95
Gogebic	~~137~~	0.95
Gd. Traverse	~~455~~	0.95
Gratiot	~~209~~	0.95
Hillsdale	~~233~~	0.95
Houghton/Keweenaw	~~222~~	0.95
Huron	~~237~~	0.95

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APPENDIX ~~B~~ C - continued

Planning Area	~~Bed~~ Need	ADC Adjustment Factor
Ingham	~~1,048~~	0.95
Ionia	~~260~~	0.95
Iosco	~~204~~	0.95
Iron	~~120~~	0.~~95~~90
Isabella	~~245~~	0.95
Jackson	~~777~~	0.95
Kalamazoo	~~1,077~~	0.95
Kalkaska	~~95~~	0.90
Kent	~~2,451~~	0.95
Lake	~~88~~	0.90
Lapeer	~~375~~	0.95
Leelanau	~~159~~	0.95
Lenawee	~~524~~	0.95
Livingston	~~710~~	0.95
Luce	~~36~~	0.90
Mackinac	~~78~~	0.90
Macomb	~~4,255~~	0.95
Manistee	~~169~~	0.95
Marquette	~~338~~	0.95
Mason	~~186~~	0.95
Mecosta	~~220~~	0.95
Menominee	~~167~~	0.95
Midland	~~411~~	0.95
Missaukee	~~92~~	0.90
Monroe	~~686~~	0.95
Montcalm	~~291~~	0.95
Montmorency	~~101~~	0.~~95~~90
Muskegon	~~843~~	0.95
Newaygo	~~241~~	0.95
Oakland	~~5,630~~	0.95
Oceana	~~152~~	0.95
Ogemaw	~~134~~	0.95
Ontonagon	~~59~~	0.90
Osceola	~~127~~	0.95
Oscoda	~~72~~	0.90
Otsego	~~132~~	0.95
Ottawa	~~1,145~~	0.95

APPENDIX B - continued

Planning Area	~~Bed Need~~	ADC Adjustment Factor
Presque Isle	~~124~~	0.95
Roscommon	~~227~~	0.95
Saginaw	~~1,038~~	0.95
St. Clair	~~811~~	0.95
St. Joseph	~~290~~	0.95
Sanilac	~~250~~	0.95
Schoolcraft	~~61~~	0.90
Shiawassee	~~336~~	0.95
Tuscola	~~287~~	0.95
Van Buren	~~365~~	0.95
Washtenaw	~~1,268~~	0.95
Wexford	~~170~~	0.95
NW Wayne	~~2,305~~	0.95
SW Wayne	~~1,542~~	0.95
Detroit	~~4,140~~	0.95
~~**Statewide Total**~~	~~**46,995**~~	

APPENDIX ~~C~~D

~~CON REVIEW STANDARDS~~
~~FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT BEDS~~

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

Allegan	HILLSDALE	MASON
Alpena	Houghton	Mecosta
Benzie	IONIA	Menominee
Branch	Isabella	~~Midland~~
Chippewa	Kalkaska	Missaukee
Delta	Keweenaw	St. Joseph
Dickinson	Leelanau	Shiawassee
Grand Traverse	Lenawee	Wexford
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	~~Ionia~~	MONTCALM~~Newaygo~~
Bay	Jackson	Muskegon
Berrien	Kalamazoo	Oakland
Calhoun	Kent	Ottawa
Cass	Lapeer	Saginaw
Clinton	Livingston	St. Clair
Eaton	Macomb	Van Buren
Genesee	MIDLAND	Washtenaw
Ingham	Monroe	Wayne

Source:

~~65~~ 75 F.R., p. ~~82238~~ 37245 (~~December 27~~JUNE 28, ~~2000~~2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

APPENDIX ~~D~~E

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 ~~2000~~ 2010 U.S. Census figures.

Planning Area	Population Density Per Square Mile
Ontonagon	~~6.0~~5.11
Schoolcraft	~~7.6~~6.95
Luce	~~7.8~~7.16
Baraga	~~9.7~~9.67
~~Alger~~IRON	~~10.7~~9.76
~~Iron~~ALGER	~~11.3~~10.25
Mackinac	~~11.7~~10.45
~~Oscoda~~GOGEBIC	~~16.7~~14.35
~~Alcona~~OSCODA	~~17.4~~15.12
~~Gogebic~~ALCONA	~~15.8~~15.76
Montmorency	~~18.8~~17.36
~~Lake~~PRESQUE ISLE	~~20.0~~19.53
~~Presque isle~~LAKE	~~21.8~~20.11
~~Menominee~~CHIPPEWA	~~24.3~~21.29
~~Chippewa~~MENOMINEE	~~24.7~~22.86
Houghton/Keweenaw	~~24.7~~24.17
~~Missaukee~~CRAWFORD	~~25.5~~25.00
~~Crawford~~MISSAUKEE	~~25.6~~25.90

Source: Michigan Department of Management and Budget and the U.S. Bureau of the Census

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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) "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.

(b) "Hospice" means a health care program licensed under Part 214 of the Code, being Section 333.21401 et seq.

(c) "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.

(d) "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.

(e) "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.

(f) "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 degenerative or congenital nature. These impairments may be either temporary or permanent and cause partial or total functional disability or psychosocial adjustment.

(g) "Ventilator-dependent patient," means an individual who requires mechanical ventilatory assistance.

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

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 1,109 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) Hospice beds will be allocated 130 beds.

(iv) Ventilator-dependent beds will be allocated 179 beds.

(b) The following historical categories have been allocated 849 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.

(c) The number of beds set aside from the total statewide pool established for categories in subsection (1)(a) for a special population group shall be reduced if there has been no CON activity for that special population group during at least 6 consecutive application periods.

(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.

(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.

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 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.

(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 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 hospice patients

Sec. 6. The CON Commission determines there is a need for beds for patients requiring both hospice and long-term nursing care services 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 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) An application shall propose 30 beds or less.

(d) An applicant for beds from the special statewide pool of beds shall not be approved if any application for beds in that same planning area has been approved from the special statewide pool of beds allocated for hospice.

(2) 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.

(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.

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 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.

(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:

(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.
(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.
(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 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.

(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.

(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.

(viii) isolation techniques and procedures.

(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.

(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 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.

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.

(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 April 30, 2008 and effective on June 20, 2008.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR HOSPITAL BEDS

(By authority conferred on the CON Commission by sections 22215 and 22217 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, 333.22217, 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 hospital or (b) replacing beds in a hospital or physically relocating hospital beds from one licensed site to another geographic location or (c) increasing licensed beds in a hospital licensed under Part 215 or (d) acquiring a hospital . Pursuant to Part 222 of the Code, a hospital licensed under Part 215 is a covered health facility. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

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

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

(4) An increase in hospital beds certified for long-term care is a change in bed capacity for purposes of Part 222 of the Code and shall be subject to and reviewed under the CON Review Standards for Long-Term-Care Services.

Section 2. Definitions

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

(a) "Acquiring a hospital" means the issuance of a new hospital license as the result of the acquisition (including purchase, lease, donation, or other comparable arrangements) of a licensed and operating hospital and which does not involve a change in bed capacity.

(b) "Adjusted patient days" means the number of patient days when calculated as follows:

(i) Combine all pediatric patient days of care and obstetrics patient days of care provided during the period of time under consideration and multiply that number by 1.1.

(ii) Add the number of non-pediatric and non-obstetric patient days of care, excluding psychiatric patient days, provided during the same period of time to the product obtained in (i) above. This is the number of adjusted patient days for the applicable period.

(c) "Alcohol and substance abuse hospital" means a licensed hospital within a long-term (acute) care (LTAC) hospital that exclusively provides inpatient medical detoxification and medical stabilization and related outpatient services for persons who have a primary diagnosis of substance dependence covered by DRGs 433 - 437.

(d) "Average adjusted occupancy rate" shall be calculated as follows:

(i) Calculate the number of adjusted patient days during the most recent, consecutive 36-month period, as of the date of the application, for which verifiable data are available to the Department.

(ii) Calculate the total licensed bed days for the same 36-month period as in (i) above by multiplying the total licensed beds by the number of days they were licensed.

(iii) Divide the number of adjusted patient days calculated in (i) above by the total licensed bed days calculated in (ii) above, then multiply the result by 100.

(d) "Base year" means the most recent year that final MIDB data is available to the Department ~~unless a different year is determined to be more appropriate by the Commission~~.

(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) "Close a hospital" means an applicant will demonstrate to the satisfaction of the Department that a hospital licensed under Part 215, and whose licensed capacity for the most recent 24 months prior to submission of the application was at least 80 percent for acute care beds, will close and surrender its acute care hospital license upon completion of the proposed project.

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

(h) "Common ownership or control" means a hospital that is owned by, is under common control of, or has a common parent as the applicant hospital.

(i) "Compare group" means the applications that have been grouped for the same type of project in the same hospital group and are being reviewed comparatively in accordance with the CON rules.

(j) "Department" means the Michigan Department of Community Health (MDCH).

(k) "Department inventory of beds" means the current list maintained for each hospital group on a continuing basis by the Department of (i) licensed hospital beds and (ii) hospital beds approved by a valid CON issued under either Part 221 or Part 222 of the Code that are not yet licensed. The term does not include hospital beds certified for long-term-care in hospital long-term care units.

(l) "Disproportionate share hospital payments" means the most recent payments to hospitals in the special pool for non-state government-owned or operated hospitals to assure funding for costs incurred by public facilities providing inpatient hospital services which serve a disproportionate number of low-income patients with special needs as calculated by the Medical Services Administration within the Department.

(m) "Excluded hospitals" means hospitals in the following categories:

(i) Critical access hospitals designated by CMS pursuant to 42 CFR 485.606

(ii) Hospitals located in rural or micropolitan statistical area counties

(iii) LTAC AND INPATIENT REHABILITATION FACILITY hospitals

(iv) Sole community hospitals designated by CMS pursuant to 42 CFR 412.92

(v) Hospitals with 25 or fewer licensed beds

(n) "Existing hospital beds" means, for a specific hospital group, the total of all of the following: (i) hospital beds licensed by the Department of Licensing and Regulatory Affairs or its successor; (ii) hospital beds with valid CON approval but not yet licensed; (iii) proposed hospital beds under appeal from a final decision of the Department; and (iv) proposed hospital beds that are part of a completed application under Part 222 (other than the application under review) for which a proposed decision has been issued and which is pending final Department decision.

(o) "Gross hospital revenues" means the hospital's revenues as stated on the most recent Medicare and Michigan Medicaid forms filed with the Medical Services Administration within the Department.

(p) "Health service area" OR "HSA" means the groups of counties listed in Appendix A.

(q) "Hospital bed" means a bed within the licensed bed complement at a licensed site of a hospital licensed under Part 215 of the Code, excluding (i) hospital beds certified for long-term care as defined in Section 20106(6) of the Code and (ii) unlicensed newborn bassinets.

(r) "Hospital" means a hospital as defined in Section 20106(5) of the Code being Section 333.20106(5) of the Michigan Compiled Laws and licensed under Part 215 of the Code. The term does not include a hospital or hospital unit licensed or operated by the Department of Mental Health.

(s) "Hospital group" means a cluster or grouping of hospitals based on geographic proximity and hospital utilization patterns. The list of hospital groups and the hospitals assigned to each hospital group will be posted on the State OF Michigan CON web site and will be updated pursuant to Section 3.

(t) "Hospital long-term-care unit" or "HLTCU" means a nursing care unit, owned or operated by and as part of a hospital, licensed by the Department, and providing organized nursing care and medical treatment to 7 or more unrelated individuals suffering or recovering from illness, injury, or infirmity.

(u) "Host hospital" means a licensed and operating hospital, which delicenses hospital beds, and which leases patient care space and other space within the physical plant of the host hospital, to allow an LTAC hospital, INPATIENT REHABILITATION FACILITY HOSPITAL, or alcohol and substance abuse hospital, to begin operation.

(v) "INPATIENT REHABILITATION FACILITY HOSPITAL" OR "IRF HOSPITAL" MEANS A HOSPITAL THAT HAS BEEN APPROVED TO PARTICIPATE IN THE TITLE XVIII (MEDICARE)

PROGRAM AS A PROSPECTIVE PAYMENT SYSTEM (PPS) EXEMPT INPATIENT REHABILITATION HOSPITAL IN ACCORDANCE WITH 42 CFR PART 412 SUBPART P.

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

(w) "Limited access area" means those underserved areas with a patient day demand that meets or exceeds the state-wide average of patient days used per 50,000 residents in the base year and as identified in Appendix D. Limited access areas shall be redetermined when a new hospital has been approved or an existing hospital closes.

(x) "Long-term (acute) care hospital" or "LTAC hospital" means a hospital has been approved to participate in the Title XVIII (Medicare) program as a prospective payment system (PPS) exempt hospital in accordance with 42 CFR Part 412 SUBPART O.

(y) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396g and 1396i to 1396u.

(z) "Medicaid volume" means the number of Medicaid recipients served at the hospital as stated on the most recent Medicare and Michigan Medicaid forms filed with the Medical Services Administration within the Department.

(aa) "Michigan Inpatient Data Base" or "MIDB" means the data base compiled by the Michigan Health and Hospital Association or successor organization. The data base consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.

(bb) "New beds in a hospital" means hospital beds that meet at least one of the following: (i) are not currently licensed as hospital beds, (ii) are currently licensed hospital beds at a licensed site in one hospital group which are proposed for relocation in a different hospital group as determined by the Department pursuant to Section 3 of these standards, (iii) are currently licensed hospital beds at a licensed site in one hospital group which are proposed for relocation to another geographic site which is in the same hospital group as determined by the Department, but which are not in the replacement zone, or (iv) are currently licensed hospital beds that are proposed to be licensed as part of a new hospital in accordance with Section 6(2) of these standards.

(cc) "New hospital" means one of the following: (i) the establishment of a new facility that shall be issued a new hospital license, (ii) for currently licensed beds, the establishment of a new licensed site that is not in the same hospital group as the currently licensed beds, (iii) currently licensed hospital beds at a licensed site in one hospital group which are proposed for relocation to another geographic site which is in the same hospital group as determined by the Department, but which are not in the replacement zone, or (iv) currently licensed hospital beds that are proposed to be licensed as part of a new hospital in accordance with section 6(2) of these standards.

(dd) "Obstetrics patient days of care" means inpatient days of care for patients in the applicant's Michigan Inpatient Data Base data ages 15 through 44 with ~~drgs~~ DRGs 370 through 375 (obstetrical discharges).

(ee) "Overbedded hospital group" means a hospital group in which the total number of existing hospital beds in that hospital group exceeds the hospital group needed hospital bed supply.

(ff) "Pediatric patient days of care" means inpatient days of care for patients in the applicant's Michigan Inpatient Data Base data ages 0 through 14 excluding normal newborns.

(gg) "Planning year" means five years beyond the base year~~, established by the CON Commission,~~ for which hospital bed need is developed~~, unless a different year is determined to be more appropriate by the Commission~~.

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

(ii) "Relocate existing licensed hospital beds" for purposes of sections 6(3) and 8 of these standards, means a change in the location of existing hospital beds from the existing licensed hospital site to a different existing licensed hospital site within the same hospital group or HSA. This definition does not apply to projects involving replacement beds in a hospital governed by Section 7 of these standards.

(jj) "Remaining patient days of care" means total inpatient days of care in the applicant's Michigan Inpatient Data Base data minus obstetrics patient days of care and pediatric patient days of care.

(kk) "Replace beds" means a change in the location of the licensed hospital, ~~or~~ the replacement of a portion of the licensed beds at the same licensed site, OR THE ONE-TIME REPLACEMENT OF LESS THAN 50% OF THE LICENSED BEDS TO A NEW SITE WITHIN 250 YARDS OF THE BUILDING ON THE LICENSED SITE CONTAINING MORE THAN 50% OF THE LICENSED BEDS, WHICH MAY INCLUDE A NEW SITE ACROSS A HIGHWAY OR STREET AS DEFINED IN MCL 257.20 AND EXCLUDES A NEW SITE ACROSS A LIMITED ACCESS HIGHWAY AS DEFINED IN MCL 257.26. The hospital beds will be in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, etc.) within the replacement zone.

(ll) "Replacement zone" means a proposed licensed site that is (i) in the same hospital group as the existing licensed site as determined by the Department in accord with Section 3 of these standards and (ii) on the same site, on a contiguous site, or on a site within 2 miles of the existing licensed site if the existing licensed site is located in a county with a population of 200,000 or more, or on a site within 5 miles of the existing licensed site if the existing licensed site is located in a county with a population of less than 200,000.

(mm) "Uncompensated care volume" means the hospital's uncompensated care volume as stated on the most recent Medicare and Michigan Medicaid forms filed with the Medical Services Administration within the Department.

(nn) "Underserved area" means those geographic areas not within 30 minute drive time of an existing licensed acute care hospital with 24 hour/7 days a week emergency room services utilizing the most direct route using the lowest speed limits posted as defined by the Michigan Department of Transportation (MDOT).

(oo) "Use rate" means the number of days of inpatient care per 1,000 population during a one-year period.

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

Section 3. Hospital groups

Sec. 3. Each existing hospital is assigned to a hospital group pursuant to subsection (1).

(1) These hospital groups and the assignments of hospitals to hospital groups shall be updated by the Department every five years or at the direction of the Commission. The methodology described in "New Methodology for Defining Hospital Groups" by Paul l. Delamater, Ashton M. Shortridge, and Joseph P. Messina, 2011 shall be used as follows:

(a) For each hospital, calculate the patient day commitment index (%C – a mathematical computation where the numerator is the number of inpatient hospital days from a specific geographic area provided by a specified hospital and the denominator is the total number of patient days provided by the specified hospital using MIDB data) for all Michigan zip codes using the summed patient days from the most recent three years of MIDB data. Include only those zip codes found in each year of the most recent three years of MIDB data. Arrange observations in an origin-destination table such that each hospital is an origin (row) and each zip code is a destination (column) and include only hospitals with inpatient records in the MIDB.

(b) For each hospital, calculate the road distance to all other hospitals. Arrange observations in an origin-destination table such that each hospital is an origin (row) and each hospital is also a destination (column).

(c) Rescale the road distance origin-destination table by dividing every entry in the road distance origin-destination table by the maximum distance between any two hospitals.

(d) Append the road distance origin-destination table to the %C origin-destination table (by hospital) to create the input data matrix for the clustering algorithm.

(e) Group hospitals into clusters using the k-means clustering algorithm with initial cluster centers provided by a wards hierarchical clustering method. Iterate over all cluster solutions from 2 to the number of hospitals (*n*) minus 1.

(i) For each cluster solution, record the group membership of each hospital, the cluster center location for each of the clusters, the r^2 value for the overall cluster solution, the number of single hospital clusters, and the maximum number of hospitals in any cluster.

(ii) "k-means clustering algorithm" means a method for partitioning observations into a user-specified number of groups. It is a standard algorithm with a long history of use in academic and applied research. The approach identifies groups of observations such that the sum of squares from points to the assigned cluster centers is minimized, i.e., observations in a cluster are more similar to one another than they are to other clusters. Several k-means implementations have been proposed; the bed need methodology uses the widely-adopted Hartigan-Wong algorithm. Any clustering or data mining text will discuss k-means; one example is B.S. Everitt, S. Landau, M. Leese, & D. Stahl (2011) Cluster Analysis, 5th Edition. Wiley, 346 p.

(iii) "Wards hierarchical clustering method" means a method for clustering observations into groups. This method uses a binary tree structure to sequentially group data observations into clusters, seeking to minimize overall within-group variance. In the bed need methodology, this method is used to identify the starting cluster locations for k-means. Any clustering text will discuss hierarchical cluster analyis, including Ward's method; one example is: G. Gan, C. Ma, & J. Wu (2007) Data Clustering: Theory, Algorithms, and Applications (Asa-Siam Series on Statistics and Applied Probability). Society for Industrial and Applied Mathematics (Siam), 466 p.

(f) Calculate the incremental F score (F_{inc}) for each cluster solution (i) between 3 and n-1 letting:

$r^2_i = r^2$ of solution i

$r^2_{i-1} = r^2$ of solution i-1

k_i = number of clusters in solution i

k_{i-1} = number of clusters in solution i-1

n = total number of hospitals

where: $$F_{inc,i} = \frac{\left(\frac{r_i^2 - r_{i-1}^2}{k_i - k_{i-1}}\right)}{\left(\frac{1 - r_i^2}{n - (k_i - 1)}\right)}$$

(g) Select candidate solutions by finding those with peak values in f_{inc} scores such that $f_{inc,\,i}$ is greater than both $f_{inc,\,i-1}$ and $f_{inc,\,i+1}$.

(h) Remove all candidate solutions in which the largest single cluster contains more than 20 hospitals.

(i) Identify the minimum number of single hospital clusters from the remaining candidate solutions. Remove all candidate solutions containing a greater number of single hospital clusters than the identified minimum.

(j) From the remaining candidate solutions, choose the solution with the largest number of clusters (*k*). This solution (*k* clusters) is the resulting number and configuration of the hospital groups.

(k) Rename hospital groups as follows:

(i) For each hospital group, identify the HSA in which the maximum number of hospitals are located. In case of a tie, use the HSA number that is lower.

(ii) For each hospital group, sum the number of current licensed hospital beds for all hospitals.

(iii) Order the groups from 1 to *k* by first sorting by HSA number, then sorting within each HSA by the sum of beds in each hospital group. The hospital group name is then created by appending number in which it is ordered to "hg" (e.g., hg1, hg2, … hg*k*).

(iv) Hospitals that do not have patient records in the MIDB - identified in subsection (1)(a) - are designated as "ng" for non-groupable hospitals.

(2) For an application involving a proposed new licensed site for a hospital (whether new or replacement), the proposed new licensed site shall be assigned to an existing hospital group utilizing the methodology described in "A Methodology for Defining Hospital Groups" by Paul L. Delamater, Ashton M. Shortridge, and Joseph P. Messina, 2011 as follows:

(a) Calculate the road distance from proposed new site (*s*) to all existing hospitals, resulting in a list of *n* observations (s_n).

(b) Rescale s_n by dividing each observation by the maximum road distance between any two hospitals identified in subsection (1)(c).

(c) For each hospital group, subset the cluster center location identified in subsection (1)(e)(i) to only the entries corresponding to the road distance between hospitals. For each hospital group, the result is a list of *n* observations that define each hospital group's central location in relative road distance.

(d) Calculate the distance ($d_{K,S}$) between the proposed new site and each existing hospital group

where: $d_{k,s} = \sqrt{\left(HG_{k,1} - s_1\right)^2 + \left(HG_{k,2} - s_2\right)^2 + \left(HG_{k,3} - s_3\right)^2 + ... + \left(HG_{k,n} - s_n\right)^2}$

(e) Assign the proposed new site to the closest hospital group (HG*k*) by selecting the minimum value of $d_{k,s}$.

(f) If there is only a single applicant, then the assignment procedure is complete. If there are additional applicants, then steps (a) – (e) must be repeated until all applicants have been assigned to an existing hospital group.

(3) The Department shall amend the hospital groups to reflect: (a) approved new licensed site(s) assigned to a specific hospital group; (b) hospital closures; and (c) licensure action(s) as appropriate.

(4) As directed by the Commission, new hospital group assignments established according to subsection (1) shall supersede the previous subarea/hospital group assignments and shall be posted on the State of Michigan CON web site effective on the date determined by the Commission.

Section 4. Determination of the needed hospital bed supply

Sec. 4. (1) The determination of the needed hospital bed supply for a hospital group for a planning year shall be made using the MIDB and the methodology detailed in "New Methodology for Determining Needed Hospital Bed Supply" by Paul L. Delamater, Ashton M. Shortridge, and Joseph P. Messina, 2011 as follows:

(a) All hospital discharges for normal newborns (DRG 391 prior to 2008, DRG 795 thereafter) and psychiatric patients (ICD-9-CM codes 290 through 319, see Appendix E for ICD-10-CM Codes, as a principal diagnosis) will be excluded.

(b) For each county, compile the monthly patient days used by county residents for the previous five years (base year plus previous four years). Compile the monthly patient days used by non-Michigan residents in Michigan hospitals for the previous five years as an "out-of-state" unit. The out-of-state patient days unit is considered an additional county thereafter. Patient days are to be assigned to the month in which the patient was discharged. For patient records with an unknown county of residence, assign patient days to the county of the hospital where the patient received service.

(c) For each county, calculate the monthly patient days for all months in the planning year. For each county, construct an ordinary least squares linear regression model using monthly patient days as the dependent variable and months (1-60) as the independent variable. If the linear regression model is significant at a 90% confidence level (F-score, two tailed *p* value ≤ 0.1), predict patient days for months 109-120 using the model coefficients. If the linear regression model is not significant at a 90% confidence level (F-score, two tailed *p* value > 0.1), calculate the predicted monthly patient day demand in the planning year by finding the monthly average of the three previous years (months 25-60).

(d) For each county, calculate the predicted yearly patient day demand in the planning year. For counties with a significant regression model, sum the monthly predicted patient days for the planning year. For counties with a non-significant regression model, multiply the three year monthly average by 12.

(e) For each county, calculate the base year patient day commitment index (%c) to each hospital group. Specifically, divide the base year patient days from each county to each hospital group by the total number of base year patient days from each county.

(f) For each county, allocate the planning year patient days to the hospital groups by multiplying the planning year patient days by the %c to each hospital group from subsection (e).

(g) For each hospital group, sum the planning year patient days allocated from each county.

(h) For each hospital group, calculate the average daily census (ADC) for the planning year by dividing the planning year patient days by 365. Round each ADC value up to the nearest whole number.

(i) For each hospital group, select the appropriate occupancy rate from the occupancy table in Appendix C.

(j) For each hospital group, calculate the planning year bed need by dividing the planning year ADC by the appropriate occupancy rate. Round each bed need value up to the nearest whole number.

(2) The determination of the needed hospital bed supply for a limited access area shall be made using the MIDB and the methodology detailed in "A Methodology for Determining Needed Hospital Bed Supply" by Paul L. Delamater, Ashton M. Shortridge, And Joesph P. Messina, 2011 as follows:

(a) All hospital discharges for normal newborns (DRG 391 prior to 2008, DRG 795 thereafter) and psychiatric patients (ICD-9-CM codes 290 through 319, see Appendix E for ICD-10-CM Codes, as a principal diagnosis) will be excluded.

(b) Calculate the average patient day use rate of Michigan residents. Sum total patient days of Michigan residents in the base year and divide by estimated base year population for the state (population data available from US Census Bureau).

(c) Calculate the minimum number of patient days for designation of a limited access area by multiplying the average patient day use rate by 50,000. Round up to the nearest whole number.

(d) Follow steps outlined in Section 4(1)(b) – (d) to predict planning year patient days for each underserved area. Round up to the nearest whole number. The patient days for each underserved area are defined as the sum of the zip codes corresponding to each underserved area.

(e) For each underserved area, compare the planning year patient days to the minimum number of patient days for designation of a limited access area calculated in (c). Any underserved area with a planning year patient day demand greater than or equal to the minimum is designated as a limited access area.

(f) For each limited access area, calculate the planning year bed need using the steps outlined in Section 4(1)(h) – (j). For these steps, use the planning year patient days for each limited access area.

Section 5. Bed Need

Sec. 5. (1) The bed-need numbers shall apply to projects subject to review under these standards, except where a specific CON review standard states otherwise.

(2) The Department shall re-calculate the acute care bed need methodology in Section 4 every two years, or as directed by the Commission.

(3) ~~The Commission shall designate the base year and the future planning year which shall be utilized in applying the methodology pursuant to subsection (2).~~

~~(4)~~ The effective date of the bed-need numbers shall be established by the Commission.

(~~5~~4) 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 hospital bed inventory.

(~~6~~5) Modifications made by the Commission pursuant to this section shall not require standard advisory committee action, a public hearing, or submittal of the standard to the legislature and the governor in order to become effective.

Section 6. Requirements for approval -- new beds in a hospital

Sec. 6. (1) An applicant proposing new beds in a hospital, except an applicant meeting the requirements of subsection 2, 3, 4, or 5 shall demonstrate that it meets all of the following:

(a) The new beds in a hospital shall result in a hospital of at least 200 beds in a metropolitan statistical area county or 25 beds in a rural or micropolitan statistical area county. This subsection may be waived by the Department if the Department determines, in its sole discretion, that a smaller hospital is necessary or appropriate to assure access to health-care services.

(b) The total number of existing hospital beds in the hospital group to which the new beds will be assigned does not currently exceed the needed hospital bed supply. The Department shall determine the hospital group to which the beds will be assigned in accord with Section 3 of these standards.

(c) Approval of the proposed new beds in a hospital shall not result in the total number of existing hospital beds, in the hospital group to which the new beds will be assigned, exceeding the needed hospital bed supply. The Department shall determine the hospital group to which the beds will be assigned in accord with Section 3 of these standards.

(2) An applicant proposing to begin operation as a new LTAC hospital, IRF HOSPITAL or alcohol and substance abuse hospital within an existing licensed, host hospital shall demonstrate that it meets all of the requirements of this subsection:

(a) If the LTAC OR IRF hospital applicant described in this subsection does not meet the Title XVIII requirements of the Social Security Act for exemption from PPS as an LTAC OR IRF hospital within 12 months after beginning operation, then it may apply for a six-month extension in accordance with R325.9403 of the CON rules. If the applicant fails to meet the Title XVIII requirements for PPS exemption as an LTAC OR IRF hospital within the 12 or 18-month period, then the CON granted pursuant to this section shall expire automatically.

(b) The patient care space and other space to establish the new hospital is being obtained through a lease arrangement and renewal of a lease between the applicant and the host hospital. The initial, renewed, or any subsequent lease shall specify at least all of the following:

(i) That the host hospital shall delicense the same number of hospital beds proposed by the applicant for licensure in the new hospital or any subsequent application to add additional beds.

(ii) That the proposed new beds shall be for use in space currently licensed as part of the host hospital.

(iii) That upon non-renewal and/or termination of the lease, upon termination of the license issued under Part 215 of the act to the applicant for the new hospital, or upon noncompliance with the project delivery requirements or any other applicable requirements of these standards, the beds licensed as part of the new hospital must be disposed of by one of the following means:

(A) Relicensure of the beds to the host hospital. The host hospital must obtain a CON to acquire the LTAC OR IRF hospital. In the event that the host hospital applies for a CON to acquire the LTAC OR IRF hospital [including the beds leased by the host hospital to the LTAC OR IRF hospital] within six months following the termination of the lease with the LTAC OR IRF hospital, it shall not be required to be in compliance with the hospital bed supply if the host hospital proposes to add the beds of the LTAC OR IRF hospital to the host hospital's medical/surgical licensed capacity and the application meets all other applicable project delivery requirements. The beds must be used for general medical/surgical purposes. Such an application shall not be subject to comparative review and shall be processed under the procedures for non-substantive review (as this will not be considered an increase in the number of beds originally licensed to the applicant at the host hospital);

(B) Delicensure of the hospital beds; or

(C) Acquisition by another entity that obtains a CON to acquire the new hospital in its entirety and that entity must meet and shall stipulate to the requirements specified in Section 6(2).

(c) The applicant or the current licensee of the new hospital shall not apply, initially or subsequently, for CON approval to initiate any other CON covered clinical services; provided, however, that this section is not intended, and shall not be construed in a manner which would prevent the licensee from contracting and/or billing for medically necessary covered clinical services required by its patients under arrangements with its host hospital or any other CON approved provider of covered clinical services.

(d) The new licensed hospital shall remain within the host hospital.

(e) The new hospital shall be assigned to the same hospital group as the host hospital.

(f) The proposed project to begin operation of a new hospital, under this subsection, shall constitute a change in bed capacity under Section 1(2) of these standards.

(g) The lease will not result in an increase in the number of licensed hospital beds in the hospital group.
(h) Applications proposing a new hospital under this subsection shall not be subject to comparative review.

(3) An applicant proposing to add new hospital beds, as the receiving licensed hospital under Section 8, shall demonstrate that it meets all of the requirements of this subsection and shall not be required to be in compliance with the needed hospital bed supply if the application meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.
(a) The approval of the proposed new hospital beds shall not result in an increase in the number of licensed hospital beds as follows:
(i) In the hospital group pursuant to Section 8(2)(a), or
(ii) in the HSA pursuant to Section 8(2)(b).
(b) Where the source hospital was subject to Section 8(3)(b), the receiving hospital shall have an average adjusted occupancy rate of 40 percent or above.
(c) Where the source hospital was subject to Section 8(3)(b), the addition of the proposed new hospital beds at the receiving hospital shall not exceed the number determined by the following calculation:
(i) As of the date of the application, calculate the adjusted patient days for the most recent, consecutive 36-month period where verifiable data is available to the Department, and divide by .40.
(ii) Divide the result of subsection (i) by 1095 (or 1096, if the 36-month period includes a leap year) and round up to next whole number or 25, whichever is larger. This is the maximum number of beds that can be licensed at the receiving hospital.
(iii) Subtract the receiving hospital's total number of licensed beds and approved beds from the result of subsection (ii). This is the maximum number of beds that can be added to the receiving hospital.
(d) Where the source hospital was subject to Section 8(3)(b), the receiving hospital's average adjusted occupancy rate must not be less than 40 percent after the addition of the proposed new hospital beds.
(e) Subsection (3)(b), (c), and (d) shall not apply to excluded hospitals.
(f) The proposed project to add new hospital beds, under this subsection, shall constitute a change in bed capacity under Section 1(2) of these standards.
(g) Applicants proposing to add new hospital beds under this subsection shall not be subject to comparative review.

(4) An applicant may apply for the addition of new beds if all of the following subsections are met. Further, an applicant proposing new beds at an existing licensed hospital site shall not be required to be in compliance with the needed hospital bed supply if the application meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.
(a) The beds are being added at the existing licensed hospital site.
(b) The hospital at the existing licensed hospital site has operated at an adjusted occupancy rate of 80 percent or above for the previous, consecutive 24 months based on its licensed and approved hospital bed capacity. The adjusted occupancy rate shall be calculated as follows:
(i) Calculate the number of adjusted patient days during the most recent, consecutive 24-month period for which verifiable data are available to the Department.
(ii) Divide the number calculated in (i) above by the total possible patient days [licensed and approved hospital beds multiplied by 730 (or 731 if including a leap year)]. This is the adjusted occupancy rate.
(c) The number of beds that may be approved pursuant to this subsection shall be the number of beds necessary to reduce the adjusted occupancy rate for the hospital to 75 percent. The number of beds shall be calculated as follows:
(i) Divide the number of adjusted patient days calculated in subsection (b)(i) by .75 to determine licensed bed days at 75 percent occupancy.
(ii) Divide the result of step (i) by 730 (or 731 if including a leap year) and round the result up to the next whole number.

(iii) Subtract the number of licensed and approved hospital beds as documented on the "Department Inventory of Beds" from the result of step (ii) and round the result up to the next whole number to determine the maximum number of beds that may be approved pursuant to this subsection.

(d) A licensed acute care hospital that has relocated its beds, after the effective date of these standards, shall not be approved for hospital beds under this subsection for five years from the effective date of the relocation of beds.

(e) Applicants proposing to add new hospital beds under this subsection shall not be subject to comparative review.

(f) Applicants proposing to add new hospital beds under this subsection shall demonstrate to the Department that they have pursued a good faith effort to relocate acute care beds from other licensed acute care hospitals within the HSA. At the time an application is submitted to the Department, the applicant shall demonstrate that contact was made by one certified mail return receipt for each organization contacted.

(5) An applicant proposing a new hospital in a limited access area shall not be required to be in compliance with the needed hospital bed supply if the application meets all other applicable CON review standards, agrees and assures to comply with all applicable project delivery requirements, and all of the following subsections are met.

(a) The proposed new hospital, unless a critical access hospital, shall have 24 hour/7 days a week emergency services, obstetrical services, surgical services, and licensed acute care beds.

(b) The Department shall assign the proposed new hospital to an existing hospital group based on the current market use patterns of existing hospital groups.

(c) Approval of the proposed new beds in a hospital in a limited access area shall not exceed the bed need for the limited access area as determined by the bed need methodology in Section 4 and as set forth in Appendix D.

(d) The new beds in a hospital in a limited access area shall result in a hospital of at least 100 beds in a metropolitan statistical area county or 50 beds in a rural or micropolitan statistical area county. If the bed need for a limited access area, as shown in Appendix D, is less, then that will be the minimum number of beds for a new hospital under this provision. If an applicant for new beds in a hospital under this provision simultaneously applies for status as a critical access hospital, the minimum hospital size shall be that number allowed under state/federal critical access hospital designation.

(e) Applicants proposing to create a new hospital under this subsection shall not be approved, for a period of five years after beginning operation of the facility, of the following covered clinical services: (i) open heart surgery, (ii) therapeutic cardiac catheterization, (iii) fixed positron emission tomography (PET) services, (iv) all transplant services, (v) neonatal intensive care services/beds, and (vi) fixed urinary extracorporeal shock wave lithotripsy (UESWL) services.

(f) Applicants proposing to add new hospital beds under this subsection shall be prohibited from relocating the new hospital beds for a period of 10 years after beginning operation of the facility.

(g) An applicant proposing to add a new hospital pursuant to this subsection shall locate the new hospital as follows:

(i) In a metropolitan statistical area county, an applicant proposing to add a new hospital pursuant to this subsection shall locate the new hospital within the limited access area and serve a population of 50,000 or more inside the limited access area and within 30 minutes drive time from the proposed new hospital.

(ii) In a rural or micropolitan statistical area county, an applicant proposing to add a new hospital pursuant to this subsection shall locate the new hospital within the limited access area and serve a population of 50,000 or more inside the limited access area and within 60 minutes drive time from the proposed new hospital.

Section 7. Requirements for approval to replace beds

Sec. 7. (1) If the application involves the development of a new licensed site, an applicant proposing to replace beds in a hospital within the replacement zone shall demonstrate that the new beds in a hospital shall result in a hospital of at least 200 beds in a metropolitan statistical area county or 25 beds in

a rural or micropolitan statistical area county. This subsection may be waived by the Department if the Department determines, in its sole discretion, that a smaller hospital is necessary or appropriate to assure access to health-care services.

(2) The applicant shall specify whether the proposed project is to replace the licensed hospital to a new site, ~~or~~ to replace a portion of the licensed beds at the existing licensed site, OR THE ONE-TIME REPLACEMENT OF LESS THAN 50% OF THE LICENSED BEDS TO A NEW SITE WITHIN 250 YARDS OF THE BUILDING ON THE LICENSED SITE CONTAINING MORE THAN 50% OF THE LICENSED BEDS, WHICH MAY INCLUDE A NEW SITE ACROSS A HIGHWAY OR STREET AS DEFINED IN MCL 257.20 AND EXCLUDES A NEW SITE ACROSS A LIMITED ACCESS HIGHWAY AS DEFINED IN MCL 257.26

(3) The applicant shall demonstrate that the new licensed site is in the replacement zone.

(4) The applicant shall comply with the following requirements, as applicable:
(a) The applicant's hospital shall have an average adjusted occupancy rate of 40 percent or above.
(b) If the applicant hospital does not have an average adjusted occupancy rate of 40 percent or above, then the applicant hospital shall reduce the appropriate number of licensed beds to achieve an average adjusted occupancy rate of 60 percent or above. The applicant hospital shall not exceed the number of beds calculated as follows:
(i) As of the date of the application, calculate the number of adjusted patient days during the most recent, consecutive 36-month period where verifiable data is available to the Department, and divide by .60.
(ii) Divide the result of subsection (i) above by 1095 (or 1096 if the 36-month period includes a leap year) and round up to the next whole number or 25, whichever is larger. This is the maximum number of beds that can be licensed at the licensed hospital site after the replacement.
(c) Subsection (4)(a) and (b) shall not apply to excluded hospitals.

(5) An applicant proposing replacement beds in the replacement zone shall not be required to be in compliance with the needed hospital bed supply if the application meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.

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

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

(2) Any existing licensed acute care hospital (source hospital) may relocate all or a portion of its beds to another existing licensed acute care hospital as follows:
(a) The licensed acute care hospitals are located within the same hospital group, or
(b) the licensed acute care hospitals are located within the same HSA if the receiving hospital meets the requirements of Section 6(4)(b) of these standards.

(3) The applicant shall comply with the following requirements, as applicable:
(a) The source hospital shall have an average adjusted occupancy rate of 40 percent or above.
(b) If the source hospital does not have an average adjusted occupancy rate of 40 percent or above, then the source hospital shall reduce the appropriate number of licensed beds to achieve an average adjusted occupancy rate of 60 percent or above upon completion of the relocation(s). The source hospital shall not exceed the number of beds calculated as follows:
(i) As of the date of the application, calculate the number of adjusted patient days during the most recent, consecutive 36-month period where verifiable data is available to the Department, and divide by .60.

(ii) Divide the result of subsection (i) by 1095 (or 1096 if the 36-month period includes a leap year) and round up to the next whole number or 25, whichever is larger. This is the maximum number of beds that can be licensed at the source hospital site after the relocation.

(c) Subsections (3)(a) and (b) shall not apply to excluded hospitals.

(4) A source hospital shall apply for multiple relocations on the same application date, and the applications can be combined to meet the criteria of (3)(b) above. A separate application shall be submitted for each proposed relocation.

(5) The hospital from which the beds are being relocated, and the hospital receiving the beds, shall not require any ownership relationship.

(6) The relocated beds shall be licensed to the receiving hospital and will be counted in the inventory for the applicable hospital group.

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

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

Sec. 9. An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

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

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

(i) Not deny services to any individual based on ability to pay or source of payment.

(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) An applicant approved pursuant to Section 6(4) must achieve a minimum occupancy of 75 percent over the last 12-month period in the three years after the new beds are put into operation, and for each subsequent calendar year, or the number of new licensed beds shall be reduced to achieve a minimum of 75 percent average annual occupancy for the revised licensed bed complement.

(b) The applicant must submit documentation acceptable and reasonable to the Department, within 30 days after the completion of the 3-year period, to substantiate the occupancy rate for the last 12-month period after the new beds are put into operation and for each subsequent calendar year, within 30 days after the end of the year.

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

(d) The applicant shall participate and submit data to the Michigan Inpatient Data Base (MIDB). The data shall be submitted to the Department or its designee.

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

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

~~**Section 10. Rural, micropolitan statistical area, and metropolitan statistical area Michigan counties**~~

~~Sec. 10. Rural, micropolitan statistical area, and metropolitan statistical area Michigan counties, for purposes of these standards, are incorporated as part of these standards as Appendix B. The Department may amend Appendix B as appropriate to reflect changes by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget.~~

Section ~~11~~10. Department inventory of beds

Sec. ~~11~~10. The Department shall maintain and provide on request a listing of the Department inventory of beds for each hospital group.

Section ~~12~~11. Effect on prior planning policies; comparative reviews

Sec. ~~12~~11. (1) These CON review standards supersede and replace the CON standards for hospital beds approved by the CON Commission on ~~June 14, 2012~~MARCH 18, 2014 and effective ~~September 28, 2012~~JUNE 2, 2014.

(2) Projects reviewed under these standards shall be subject to comparative review except those projects meeting the requirements of Section 7 involving the replacement of beds in a hospital within the replacement zone and projects involving acquisition (including purchase, lease, donation or comparable arrangements) of a hospital.

Section ~~13~~12. Additional requirements for applications included in comparative reviews

Sec. ~~13~~12. (1) Except for those applications for limited access areas, any application for hospital beds, that is subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards shall be grouped and reviewed comparatively with other applications in accordance with the CON rules.

(2) Each application in a comparative review group shall be individually reviewed to determine whether the application is a qualifying project. If the Department determines that two or more competing applications are qualifying projects, it shall conduct a comparative review. The Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section 22225(1) of the Code, and which have the highest number of points when the results of subsection (3) are totaled. If two or more qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects that, when taken together, do not exceed the need in the order in which the applications were received by the Department based on the date and time stamp placed on the applications by the department in accordance with rule 325.9123.

(3)(a) A qualifying project will be awarded points based on the percentile ranking of the applicant's uncompensated care volume and as measured by percentage of gross hospital revenues as set forth in the following table. The applicant's uncompensated care volume will be the cumulative of all currently licensed Michigan hospitals under common ownership or control with the applicant that are located in the same health service area as the proposed hospital beds. If a hospital under common ownership or control with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero. The source document for the calculation shall be the most recent Cost Report filed with the Department for purposes of calculating disproportionate share hospital payments.

Percentile Ranking	Points Awarded
90.0 – 100	25 pts
80.0 – 89.9	20 pts
70.0 – 79.9	15 pts
60.0 – 69.9	10 pts
50.0 – 59.9	5 pts

Where an applicant proposes to close a hospital(s) as part of its application, data from the hospital(s) to be closed shall be excluded from this calculation.

(b) A qualifying project will be awarded points based on the health service area percentile rank of the applicant's Medicaid volume as measured by percentage of gross hospital revenues as set forth in the

following table. For purposes of scoring, the applicant's Medicaid volume will be the cumulative of all currently licensed Michigan hospitals under common ownership or control with the applicant that are located in the same health service area as the proposed hospital beds. If a hospital under common ownership or control with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero. The source document for the calculation shall be the most recent Cost Report filed with the department for purposes of calculating disproportionate share hospital payments.

percentile rank	points awarded
87.5 – 100	20 pts
75.0 – 87.4	15 pts
62.5 – 74.9	10 pts
50.0 – 61.9	5 pts
less than 50.0	0 pts

Where an applicant proposes to close a hospital(s) as part of its application, data from the hospital(s) to be closed shall be excluded from this calculation.

(c) A qualifying project shall be awarded points as set forth in the following table in accordance with its impact on inpatient capacity. If an applicant proposes to close a hospital(s), points shall only be awarded if (i) closure of that hospital(s) does not create a bed need in any hospital group as a result of its closing; (ii) the applicant stipulates that the hospital beds to be closed shall not be transferred to another location or facility; and (iii) the utilization (as defined by the average daily census over the previous 24-month period prior to the date that the application is submitted) of the hospital to be closed is at least equal to 50 percent of the size of the proposed hospital (as defined by the number of proposed new licensed beds).

Impact on Capacity	Points Awarded
Closure of hospital(s)	25 pts
Closure of hospital(s) which creates a bed need	-15 pts

(d) A qualifying project will be awarded points based on the percentage of the applicant's historical market share of inpatient discharges of the population in an area which will be defined as that area circumscribed by the proposed hospital locations defined by all of the applicants in the comparative review process under consideration. This area will include any zip code completely within the area as well as any zip code which touches, or is touched by, the lines that define the area included within the figure that is defined by the geometric area resulting from connecting the proposed locations. In the case of two locations or one location or if the exercise in geometric definition does not include at least ten zip codes, the market area will be defined by the zip codes within the county (or counties) that includes the proposed site (or sites). Market share used for the calculation shall be the cumulative market share of the population residing in the set of above-defined zip codes of all currently licensed Michigan hospitals under common ownership or control with the applicant**,** which are in the same health service area.

Percent	Points Awarded
% of market share	% of market share served x 30 (total pts. awarded)

The source for calculations under this criterion is the MIDB.

Section ~~14~~13. Review standards for comparative review of a limited access area

Sec. ~~14~~13. (1) Any application subject to comparative review, under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and reviewed comparatively with other applications in accordance with the CON rules.

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

(3)(a) A qualifying project will be awarded points based on the percentile ranking of the applicant's uncompensated care volume as measured by percentage of gross hospital revenues as set forth in the following table. For purposes of scoring, the applicant's uncompensated care will be the cumulative of all currently licensed Michigan hospitals under common ownership or control with the applicant. The source document for the calculation shall be the most recent Cost Report submitted to MDCH for purposes of calculating disproportionate share hospital payments. If a hospital under common ownership or control with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero.

Percentile Ranking	Points Awarded
90.0 – 100	25 pts
80.0 – 89.9	20 pts
70.0 – 79.9	15 pts
60.0 – 69.9	10 pts
50.0 – 59.9	5 pts

Where an applicant proposes to close a hospital as part of its application, data from the closed hospital shall be excluded from this calculation.

(b) A qualifying project will be awarded points based on the statewide percentile rank of the applicant's Medicaid volume as measured by percentage of gross hospital revenues as set forth in the following table. For purposes of scoring, the applicant's Medicaid volume will be the cumulative of all currently licensed Michigan hospitals under common ownership or control with the applicant. The source documents for the calculation shall be the Cost Report submitted to MDCH for purposes of calculating disproportionate share hospital payments. If a hospital under common ownership or control with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero.

Percentile Rank	Points Awarded
87.5 – 100	20 pts
75.0 – 87.4	15 pts
62.5 – 74.9	10 pts
50.0 – 61.9	5 pts
Less than 50.0	0 pts

Where an applicant proposes to close a hospital as part of its application, data from the closed hospital shall be excluded from this calculation.

(c) A qualifying project shall be awarded points as set forth in the following table in accordance with its impact on inpatient capacity in the health service area of the proposed hospital site.

Impact on Capacity	Points Awarded
Closure of hospital(s)	15 pts
Move beds	0 pts
Adds beds (net)	-15 pts
or	
Closure of hospital(s) or delicensure of beds which creates a bed need	
or	
Closure of a hospital which creates a new Limited Access Area	

(d) A qualifying project will be awarded points based on the percentage of the applicant's market share of inpatient discharges of the population in the limited access area as set forth in the following table. Market share used for the calculation shall be the cumulative market share of Michigan hospitals under common ownership or control with the applicant.

Percent	Points Awarded
% of market share	% of market share served x 15 (total pts awarded)

The source for calculations under this criterion is the MIDB.

(e) A qualifying project will be awarded points based on the percentage of the limited access area's population within a 30 minute travel time of the proposed hospital site if in a metropolitan statistical area county, or within 60 minutes travel time if in a rural or micropolitan statistical area county as set forth in the following table.

Percent	Points Awarded
% of population within 30 (or 60) minute travel time of proposed site	% of population covered x 15 (total pts awarded)

(f) All applicants will be ranked in order according to their total project costs as stated in the CON application divided by its proposed number of beds in accordance with the following table.

Cost Per Bed	Points Awarded
Lowest cost	10 pts
2nd Lowest cost	5 pts
All other applicants	0 pts

Section ~~15~~14. Requirements for approval -- acquisition of a hospital

Sec. ~~15~~14. (1) An applicant proposing to acquire a hospital shall not be required to be in compliance with the needed hospital bed supply for the hospital group in which the hospital subject to the proposed acquisition is assigned if the applicant demonstrates that all of the following are met:

(a) the acquisition will not result in a change in bed capacity,

(b) the licensed site does not change as a result of the acquisition,

(c) the project is limited solely to the acquisition of a hospital with a valid license, and

(d) if the application is to acquire a hospital, which was proposed in a prior application to be established as an LTAC OR IRF hospital and which received CON approval, the applicant also must meet

the requirements of Section 6(2). Those hospitals that received such prior approval are so identified on the Department inventory of beds.

(2) The applicant shall comply with the following requirements, as applicable:

(a) The existing licensed hospital shall have an average adjusted occupancy rate of 40 percent or above.

(b) If the existing licensed hospital does not have an average adjusted occupancy rate of 40 percent or above, the applicant shall agree to all of the following:

(i) The hospital to be acquired will achieve an annual adjusted occupancy of at least 40% during any consecutive 12-month period by the end of the third year of operation after completion of the acquisition. Annual adjusted occupancy shall be calculated as follows:

(a) Calculate the number of adjusted patient days during the most recent, consecutive 12-month period for which verifiable data is available to the Department.

(b) Divide the number of adjusted patient days calculated in (a) above by 365 (or 366 if a leap year).

(c) If the hospital to be acquired does not achieve an annual adjusted occupancy of at least 40 percent, as calculated in (b) above, during any consecutive 12-month period by the end of the third year of operation after completion of the acquisition, the applicant shall relinquish sufficient beds at the existing hospital to raise its adjusted occupancy to 60 percent. The revised number of licensed beds at the hospital shall be calculated as follows:

(i) Calculate the number of adjusted patient days during the most recent, consecutive 12-month period where verifiable data is available to the Department, and divide by .60.

(ii) Divide the result of subsection (i) above by 365 (or 366 if the 12-month period includes a leap year) and round up to the next whole number or 25, whichever is larger. This is the maximum number of beds that can be licensed at the existing licensed hospital site after acquisition.

(d) Subsection (2) shall not apply to excluded hospitals.

Section ~~16~~15. Requirements for approval – all applicants

Sec. ~~16~~15. (1) An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

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

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

APPENDIX A

Counties assigned to each health service area are as follows:

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

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

Allegan	HILLSDALE	MASON
Alpena	Houghton	Mecosta
Benzie	IONIA	Menominee
Branch	Isabella	~~Midland~~
Chippewa	Kalkaska	Missaukee
Delta	Keweenaw	St. Joseph
Dickinson	Leelanau	Shiawassee
Grand Traverse	Lenawee	Wexford
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	~~Ionia~~	MONTCALM~~Newaygo~~
Bay	Jackson	Muskegon
Berrien	Kalamazoo	Oakland
Calhoun	Kent	Ottawa
Cass	Lapeer	Saginaw
Clinton	Livingston	St. Clair
Eaton	Macomb	Van Buren
Genesee	MIDLAND	Washtenaw
Ingham	Monroe	Wayne

Source:

~~65~~ 75 F.R., p. ~~82238~~ 37245 (~~December 27~~JUNE 28, ~~2000~~2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

OCCUPANCY RATE TABLE

HOSPITAL GROUP PROJECTED BED ADC			ADJUSTED BED RANGE	
ADC _LOW	ADC_HIGH	OCCUPANCY RATE	BEDS_LOW	BED S_HIGH
30	31	60%	50	52
32	35	61%	53	58
36	39	62%	59	53
40	45	63%	64	72
46	50	64%	72	79
51	58	65%	79	90
59	67	66%	90	102
68	77	67%	102	115
78	88	68%	115	130
89	101	69%	129	147
102	117	70%	146	168
118	134	71%	167	189
135	154	72%	188	214
155	176	73%	213	242
177	204	74%	240	276
205	258	75%	274	344
259	327	76%	341	431
328	424	77%	426	551
425	561	78%	545	720
562	760	79%	712	963
761	895	80%	952	1119

~~APPENDIX D~~

LIMITED ACCESS AREAS

Limited access areas and the hospital bed need, effective ~~September 28, 2012~~(insert new effective date), for each of those areas are identified below. The hospital bed need for limited access areas shall be changed by the Department in accordance with section 2(1)(w) of these standards, and this appendix shall be updated accordingly.

LIMITED ACCESS AREA	BED NEED	PREDICTED PATIENT DAYS
1 Upper Peninsula	~~255~~196	~~68,551~~51,102
2 West Northern Lower Peninsula~~East/Central Northern Lower Peninsula~~	~~35,754~~84,639	~~143~~310
3~~ West Northern Lower Peninsula~~ East/Central Northern Lower Peninsula	~~106,135~~31,383	~~383~~127
~~4 East Southern Lower Peninsula~~	~~131~~	~~32,720~~

Sources:

1) Michigan State University
   Department of Geography
   ~~2012 REPORT: Hospital Groups, Determination of Needed Hospital Bed Supply,~~ACUTE CARE HOSPITAL BED NEED and Limited Access Areas – 2014 UPDATE
   August ~~22~~6, ~~2012~~2014

2) Section 4 of these standards

ICD-9-CM TO ICD-10-CM Code Translation

ICD-9 CODE	Description	ICD-10 Code	Description
290 through 319	Psychiatric Patients	F01.50-F99	Mental, Behavioral, and Neurodevelopmental Disorders

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

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

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INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE & AGRICULTURAL IMPLEMENT WORKERS OF AMERICA – UAW

DENNIS D. WILLIAMS, *PRESIDENT* GARY CASTEEL, *SECRETARY-TREASURER*
VICE-PRESIDENTS: CINDY ESTRADA • NORWOOD JEWELL • JIMMY SETTLES

September 18, 2014

Chairperson Keshishian, MD and Certificate of Need Commission
Capital View Building, 7th Floor
201 Townsend
Lansing, MI 48913

Mr. Chairman,

The Cardiac Catheterization Standard Advisory Committee (SAC) was approved by the Commission on January 28, 2014 and had its initial meeting on June 18, followed by meetings on July 16 and September 10. During these meetings, the SAC considered the charge approved by the Commission:

At a minimum, the Cardiac Catheterization Services SAC should consider reviewing and recommending any necessary changes to the Cardiac Catheterization Services Standards regarding the following:

1. Determine if elective therapeutic cardiac catheterizations should be allowed at facilities that do not provide on-site open heart surgery services by considering the recommendations of national organizations. If it is recommended that these services should be allowed:
    a. consider the impacts of cost, quality and access under the current standards in determining need for this service; and
    b. provide specific criteria for this service including initiation and maintenance volumes as well as patient safety and quality criteria.
2. Develop language for a second acquisition, similar to that of other standards.
3. Develop specific measurable quality metrics in the project delivery requirements, similar to that of Open Heart Surgery (OHS) standards.
4. Consider any technical or other changes from the Department, e.g., updates or modifications consistent with other CON review standards and the Public Health Code.

During the first of the three meetings, the SAC formed subcommittees to address the components of the charge, i.e., Science and Prevalence, Quality and Access, and Cost. The subcommittees reviewed and presented research and data related to therapeutic cardiac catheterizations. The SAC has heard presentations from a number of experts, including Dr. Hitinder Gurm from BMC2, Paul Delamater, Michigan State University (MSU), and Dr. Greg Dehmer, Chair and senior author of the SCAI/ACC/AHA Expert Consensus Document: "2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup" (expected at the October meeting). Based on the expert information and recommendations from the subcommittees, the SAC is expected to make recommendations in response to the charge during its October meeting. It is anticipated that the SAC recommendations will be presented to the CON following its November meeting.

Respectfully submitted,

Renee Turner-Bailey

Renee Turner-Bailey, M.H.S.A.
International Union, UAW

9-15-2014 Megavoltage Radiation Therapy (MRT) Services/Units Standards

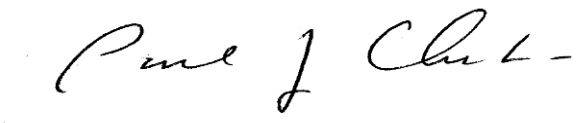
Two meetings have been held, July 30, 2014 and August 28, 2014. The next meeting is scheduled for October 2 2014. Please recall that the charge approved by the CON commission chairperson Jan 28 2014 included 6 areas to review and make recommendations.

1. Update and clarify the definition of a "special purpose MRT unit" to reflect new technologies.
    a. The consensus of the group appears to follow the statement: A special purpose MRT unit is one that is dedicated to providing radiosurgery (1-5 fractions), total body irradiation, total skin irradiation, or IORT.
    b. If a unit is dedicated to providing radiosurgery, the consensus has been that "dedicated" means that 90 percent of cases performed on the unit would be for radiosurgery (1-5 fractions)/total body irradiation/or IMRT and only 10 percent for conventional treatments. Otherwise, this would be considered as a non-special unit.
    c. There appears to be consensus that 'stand-alone' special purpose MRT services in which the only device(s) are special purpose units should be disallowed.
    d. There is a proposal that an existing non-special MRT unit could be replaced by a special MRT unit but not vice versa. This would only be permissible if a center has more than one MRT unit.
    e. There is currently a contractual obligation with a neurosurgeon required in order to have a cyberknife or gamma knife. It is proposed to eliminate this section.
    f. I expect that specific language addressing these changes will be voted on in the next meeting.
2. Review and revise the current definition and use of a "Cyber Knife."
    a. Until recently, Cyber Knife was used exclusively for radiosurgery applications, the addition of multileaf collimator to this device may facilitate treatment with conventional fractionation as well.
    b. There is consensus that use of a trade name such as "Cyber Knife" or "Gamma Knife" in the standards should be avoided. Such units would be defined as either dedicated radiosurgery devices (i.e. more than 90 percent of cases treated in 1-5 fractions), or alternatively (in the case of a cyberknife) could be designated as non-special unit. In that instance, the somewhat more stringent requirements of non-special unit would apply.
    c. I expect that specific language addressing these changes will be voted on in the next meeting.
3. Determine and add language that addresses the expansion of more than one special purpose MRT unit.
    a. It is proposed that expansion of a service could include more than one "special purpose MRT unit." A service would include at least one non-special unit but more than one special purpose unit could be allowed.
    b. I expect specific language regarding this change will be voted on in the next meeting.
4. Consider methodologies of need that utilize patient residence data.
    a. The purpose of this charge appears to be to make it easier for new MRT services to emerge in rural or underserved areas.
    b. The Department has provided data showing that less than 2 percent of the population travels significant distance for radiation treatment.
    c. The Department is currently attempting an analysis to determine if for example, early stage breast cancer patients may choose mastectomy instead of lumpectomy and radiation based on geographic location. This would imply a problem with access to MRT facilities.

d. The argument was made that previous workgroups made it easier for rural areas to start-up radiation services. However, economic factors rather than CON standard requirements have inhibited this.
e. It is possible that the number of driving miles required for (reducing the ETV requirement from 8000 to 5500) could be reduced. Currently in a rural or micropolitan statistical area county, the site of a proposed MRT service should be 60 driving miles or more. For a hospital located more than 90 miles from an MRT service, there is no ETV requirement.
f. I expect that specific language would be voted on at the next meeting.

5. Develop specific measurable quality metrics in the project delivery requirements.
    a. Quality metrics currently defined in the project delivery requirements include:
        i. Evidence of a cancer treatment program approved by the American College of Surgeons Commission on Cancer.
        ii. Evidence of accreditation by the American College of Surgeons on Cancer, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), or the Healthcare Facilities Accreditation Program (HCAP) within the first three years of operation and continue to participate annually thereafter.
        iii. Evidence of accreditation by the American College of Radiology/American Society for Radiation Oncology (ACR/ASTRO) or the American College of Radiation Oncology within the first three years of operation and continue to participate annually thereafter.
    b. There was also public comment regarding the possibility of additional requirements to address quality especially with respect to the use of intensity modulated radiation therapy.
    c. The consensus of the SAC appears to be that the current accreditation requirements insure safety and quality.
6. Consider any technical or other changes from the Department, e.g., updates or modifications consistent with other CON review standards and the Public Health Code.
    a. The department has presented the proposed updates and modifications without objection.
    b. I expect specific language to be voted on at the next meeting.

Respectfully Submitted,



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STATE OF MICHIGAN

RICK SNYDER, Governor

Michigan Certificate of Need Commission

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MEMORANDUM

Date: August 7, 2014

To: Joint Legislative Committee (JLC)

From: Certificate of Need (CON) Commission

RE: Recommendations Pertaining to the CON Program

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

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

The Commission respectfully submits the following:

Based on our continuous review of the program, the Commission believes and unanimously recommends that the program should be fully supported as it is serving a valuable need. In our bipartisan judgment, we strongly believe the current CON process meets the three statutory objectives for the program, i.e., affordability, accessibility, and quality of health care in Michigan. Members of the Commission as well as staff met with members of the Legislature throughout the past two years and in particular during the summer of 2013 during the House of Representatives CON Workgroup. Commissioners, including the Chairperson and Vice-Chairperson, were available to the House of Representatives CON Workgroup to assist in explaining CON history and processes as well as providing input to the deliberations. As a result, the House of Representatives CON Workgroup decided that due to its complexity, the CON process needed further evaluation if any changes are to be recommended. The Commission supports this finding, and we look forward to working with the Legislature to assist in the evaluation.

In addition to the responsibility of submitting the 2-year report to the JLC, MCL 333.22215(1)(e) of the CON law requires the Commission to "Annually assess the operations and effectiveness of the certificate of need program based on periodic reports from the department and other information available to the commission." Copies of FY2013 and FY2014 CON Program Annual Activity Reports are being provided with this Memo. Along with these annual reports, the Department provides quarterly program section performance reports to the Commission. These reports demonstrate the effectiveness of the CON program in processing letters of intent, applications, emergency applications, and amendments, as well as issuing decisions within the specified time frames set forth in the Administrative Rules.

Pursuant to MCL 333.22215 (1)(m), the CON Commission is to "… review and, if necessary, revise each set of certificate of need review standards at least every 3 years." A Public Comment Period is held in October prior to the review year to determine what, if any, changes need to be made for each standard scheduled for review. The following review standards are up for review in 2015: Bone Marrow Transplantation (BMT) Services, Heart/Lung and Liver Transplantation Services, Magnetic Resonance Imaging (MRI) Services, Psychiatric Beds and Services. Currently, there are Standard Advisory Committees (SACs) reviewing CON Review Standards for Cardiac Catheterization Services and CON Review Standards for Megavoltage Radiation Therapy (MRT) Services/Units. There is a workgroup reviewing CON Review Standards for Positron Emission Tomography (PET) Scanner Services. The Commission actively seeks input from the public and always includes opportunities for public comment/hearings prior to any Commission action.

We would like to provide the JLC a brief summary of our activities and accomplishments since the January, 2013 report. In the last two years, the Commission has updated 13 of the 15 Review Standards for covered services. In some instances, technical changes were made to modernize standards. For example, all applicable standards were updated to include International Disease Codes version 10 conversion charts to reflect the healthcare industry transition to this new diagnosis coding system. In other instances, major changes were made to benefit the cost, quality and access of healthcare for Michigan citizens. Some examples include specific quality measures added to Open Heart Surgery Standards, the inclusion of national safety standards for Special Newborn Nursing Services in the Neonatal Intensive Care Unit (NICU) Standards, and revision to the Computed Tomography (CT) methodology to reflect current coding practices that will ensure better accuracy in determining need. All of these changes, both technical and policy, have been made with the multiple opportunities for public input and with the recommendations of subject matter experts.

Further, in continuing to fulfill our legislative charge in MCL 333.22215 (1)(a) to “revise, add to, or delete one or more of the covered clinical services”, the Commission engaged in discussion to end the CON regulation of Air Ambulance Services due to federal law that limits the ability for states to limit the number of Air Ambulance services with need-based standards. The Commission worked closely with the Emergency Medical Services administration to determine a path to continue regulating the quality of Air Ambulance services through already established programs within the Department while defining a strategy for discontinuing CON oversight at the appropriate time. A summary of all of the approved changes to various CON Review Standards is attached.

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

Respectfully yours,

Marc D. Keshishian, MD, Chairperson

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

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c: James Haveman, Director, MDCH
Nick Lyon, Chief Deputy Director, MDCH
Elizabeth Hertel, Director of Health Policy and Innovation, MDCH
Joseph Potchen, First Assistant Attorney General, Attorney General's Office
Scott Blakeney, Director, Health Policy and Organizational Support, MDCH
Tulika Bhattacharya, Manager, CON Evaluation Section, MDCH
Beth Nagel, Manager, Planning and Access to Care Section, MDCH
Brenda Rogers, Special Assistant to the CON Commission, Planning and Access to Care Section, MDCH

Attachment

SUMMARY OF CON REVIEW STANDARDS REVISIONS
(FY2013 – FY2014)

During FY2013, the Certificate of Need Commission revised the review standards for Bone Marrow Transplantation (BMT) Services, Magnetic Resonance Imaging (MRI) Services, Megavoltage Radiation Therapy (MRT) Services/Units, and Psychiatric Beds and Services.

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

- Section 1 - Modified for consistency with other CON review standards.
- Section 2 - Definitions used only in certain section(s) were moved to the applicable section to make it easier for the reader to identify the defined terms, and other definitions were updated.
    - "Acquisition of a BMT service" was moved to Section 4.
    - "Initiate a BMT service" was moved to Section 3.
- Section 6 - Updated Medicaid participation section consistent with other CON review standards.
- Section 7 - Divided project delivery requirements into distinct groups (quality assurance, access to care, and monitoring and reporting).
- Appendix A - Health Service Areas moved to an Appendix consistent with other CON review standards.
- Other technical changes.

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

- Section 2 - Definitions were modified and/or moved to applicable section.
- Section 4 - Clarified replace and upgrade definitions. Added a new definition for "repair an existing MRI unit." This is to allow components of an MRI unit to be repaired if under a service/maintenance agreement.
    - Under subsection (3), added a one-time replacement of an existing MRI unit that is below 1 tesla with an MRI unit that is a 1 tesla or higher outside of volume requirements.
    - Under subsection (4), added requirements to allow replacement of an existing mobile MRI host site to a new location similar to other CON standards.
- Section 7 - Modified for consistency with other CON review standards in that the applicant agrees that the dedicated research MRI unit will be used primarily (70% or more of the procedures) for research purposes only.
- Section 11 - Added requirements similar to intraoperative MRI (IMRI) to initiate, replace, or acquire an MRI simulator that will not be used solely for MRT treatment planning purposes.
- Section 14 - Divided requirements into distinct groups consistent with other standards (quality assurance, access to care, and monitoring and reporting).
    - Under subsection (2)(d)(i)(D), revised to align with the "American College of Radiology (ACR) Practice Guideline for Performing and Interpreting Magnetic Resonance Imaging (MRI)" language on MRI accreditation to ensure consistency with national standards.

    - Under subsection (4)(b), added reporting requirement for MRI simulators approved under Section 11.
- Section 15 - Increased the base value for functional MRI (fMRI) procedures, MRI-guided interventions, and cardiac MRI procedures, and added definitions for these procedures too.
- Other technical edits.

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

- Section 2 - Definitions were eliminated as they are no longer necessary, and a new definition was added.
    - "Excess Equivalent Treatment Visits (ETVs)" means the number of ETVs performed by an existing MRT service in excess of 10,000 per MRT unit. The number of MRT units used to compute excess ETVs shall include both existing and approved but not yet operational MRT units. In the case of an MRT service that operates or has a valid CON to operate that has more than one MRT unit at the same site, the term means number of ETVs in excess of 10,000 multiplied by the number of MRT units at the same site. For example, if an MRT service operates, or has a valid CON to operate, two MRT units at the same site, the excess ETVs is the number that is in excess of 20,000 (10,000 x 2) ETVs.
- Old Section 3 - Eliminated as it's no longer needed due to other changes within the standard.
- New Section 3 - Added language to allow for greater geographic access in Planning Area 8. An applicant will be exempt from projecting ETVs for initiation if it meets other specific criteria.
- Section 9 - New methodology for projecting ETVs – projections will be based on the historical MRT volume of treating physicians. "Treating physician" is defined as the staff physician of the MRT service directing and providing the MRT treatment, not the referring physician. This models the language in the CON Review Standards for Computed Tomography (CT) Scanner Services.
- Old sections 12 and 13 - Eliminated as they are no longer needed due to other changes within the standard.
- New Section 11 - Added requirements to be accredited 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) and to be accredited by the American College of Radiology/American Society for Radiation Oncology (ACR/ASTRO) or the American College of Radiation Oncology (ACRO).
    - Under subsection (4)(b), MRT units approved pursuant to Section 3(3) in Planning Area 8 shall be operating at a minimum average volume of 5,500 ETVs annually.
- Old Appendices A and B - Eliminated as they are no longer needed.
- Other technical changes.

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

- Section 1 - Modified for consistency with other CON review standards.

- Section 2 - Definitions were modified and new definitions were added.
    - "Flex bed" is defined as an existing adult psychiatric bed converted to a child/adolescent psychiatric bed in an existing child/adolescent psychiatric service to accommodate during peak periods and meet patient demand.
    - "Relocate existing licensed inpatient psychiatric beds" means a change in the location of existing inpatient psychiatric beds from the existing licensed psychiatric hospital site to a different existing licensed psychiatric hospital site within the same planning area. This definition does not apply to projects involving replacement beds in a psychiatric hospital or unit governed by Section 7 of these standards.
- Section 3 - The bed need methodology was run using the base year of 2010 and a planning year of 2015 (The bed need numbers were given immediate effect).
- Section 4 - Updated consistent with other standards and current practice. The bed need numbers will continue to be posted on the web site as part of the Psychiatric bed inventory, and the appendix in the standards will be eliminated.
- Section 7 - Modified for consistency with other CON review standards.
- Section 8 - Added requirements to allow for relocation of existing licensed inpatient psychiatric beds consistent with other standards.
- Section 9 – Requirements for approval to increase beds were updated.
    - Under subsection (2), defined calculation for average occupancy rate and modified the time period from 24 months to 12 months.
    - Under subsection (3), modified the time period from 24 months to 12 months and added a calculation for high occupancy for facilities with flex beds.
    - Added requirements under subsection (10) for a facility receiving licensed inpatient psychiatric beds under relocation (Section 8) consistent with other standards.
- Section 10 - Added new section for flex beds. This will allow for a facility with an existing adult psychiatric service and an existing child/adolescent psychiatric service to convert adult psychiatric beds to child/adolescent psychiatric beds to accommodate during peak periods and meet patient demand.
    - The existing adult psychiatric service/unit shall not become non-compliant with the minimum size requirements within section 6(4).
    - The applicant shall meet all applicable sections of the standards.
    - The facility shall be in compliance and meet all design standards of the most recent Minimum Design Standards for Health Care Facilities in Michigan.
    - The applicant shall convert the beds back to adult inpatient psychiatric beds if the bed has not been used as a flex bed serving a child/adolescent patient for a continuous 12-month period or if the CON application is withdrawn.
- Section 14 - Divided requirements into distinct groups consistent with other standards (quality assurance, access to care, and monitoring and reporting).
    - Under subsection (4), added the calculation for average occupancy.
- Updated/eliminated Appendices as applicable.
- Other technical changes.

During FY2014, the CON Commission revised the review standards for Air Ambulance Services, Bone Marrow Transplantation (BMT) Services, Cardiac Catheterization Services, Computed Tomography (CT) Services, Hospital Beds, Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services, Open Heart Surgery (OHS) Services, Positron Emission

Tomography (PET) Scanner Services, and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units.

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

- Section 1: Modified for consistency with other CON review standards. Relocation is a part of replacement.
- Section 2: Definitions have been moved to applicable sections if only used in that section. "Medicaid" definition has been removed as it is defined in Part 222 of the Public Health Code.
- Section 3: Removed "need" requirements for initiation.
- Section 4: Moved from Section 5 and removed "need" requirements for replacement. Added subsection (5) as a technical edit consistent with initiation and acquisition.
- Section 5: Moved from Section 4 and removed "need" requirements for expansion. Added subsection (4) as a technical edit consistent with initiation and acquisition.
- Section 6: Removed "need" requirements for acquisition.
- Section 8: Divided requirements into distinct groups consistent with other standards: quality assurance, access to care, and monitoring and reporting.
    - Under subsection (2), removed "need" based requirement for 275 patient transports annually.
- Section 9: "Need" based methodology removed.
- Other technical edits.
- Note: Due to federal law preventing states from regulating air ambulance based on need, all need requirements were removed.

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

- Section 2(1)(e): "Cancer Hospital" is being redefined and "means a hospital that has been approved as a comprehensive cancer center 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."
- Section 4(1): Updated to reflect the removal of the PPS exemption requirement for acquisition by a cancer hospital.
- Section 4(2): Language added to allow for reacquisition of a BMT service by the current CON holder.
- Section 10(1): Technical edits.

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

- Section 2: Definition moved to applicable Appendix.
- Subsection (1)(k): Modified for the ICD-9-CM to ICD-10-CM Code translation.
- Appendix B: Added new Appendix for the ICD-9-CM to ICD-10-CM Code translation.
- Other technical edits.

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

- Section 1: Modified for consistency with other CON review standards. Relocation is a part of replacement.
- Section 2: Definitions have been modified, definitions moved to applicable sections if only used in that section, and new definitions have been added.
    - "Billable procedure" has been modified.
    - "Bundled body scan" is a new definition and is defined as "two or more body scans billed as one CT procedure.
    - "CT-angio hybrid unit" is a new definition and is defined as "an integrated system comprised of both CT and angiography equipment sited in the same room that is designed specifically for interventional radiology or cardiac procedures. The CT unit is a guidance mechanism and is intended to be used as an adjunct to the procedure. The CT unit shall not be used for diagnostic studies unless the patient is currently undergoing a CT-angio hybrid procedure and is in need of a secondary diagnostic study."
    - "Initiate a CT scanner service" has been modified as relocation is a part of replacement.
    - "Metropolitan statistical area county" is included in Appendix B.
    - "Micropolitan statistical area county" is included in Appendix B.
    - Relocation terms combined with replacement terms and/or section.
    - "Replace an existing CT scanner" modified to include relocation.
    - "Rural county" is included in Appendix B.
- Section 3: Under new subsection (4), added requirements to initiate CT scanner services as an existing host site on a different mobile CT scanner service consistent with other CON review standards.
- Section 4: Modified to include initiation of mobile dental CT scanner services.
    - Under new subsection (6), added requirements to initiate mobile dental CT scanner services as an existing host site on a different mobile dental CT scanner service consistent with other CON review standards.
- Section 6: Modified to include expansion of an existing mobile dental CT scanner service.
- Section 7:
    - Removed volume requirements for replacement of an existing fixed, mobile, or dedicated pediatric CT scanner.
    - New subsection (2) moved from old Section 9(1) and modified accordingly consistent with other CON review standards.
    - New subsection (3) moved from old Section 9(2) and modified accordingly consistent with other CON review standards.
- Section 8:
    - Removed volume requirements for replacement of an existing dental CT scanner or service.
    - New subsection (2) moved from old Section 10(1) and modified accordingly consistent with other CON review standards.
    - New subsection (3) moved from old Section 10(2) and modified accordingly consistent with other CON review standards.
- Section 9: Modified acquisition volume requirement of 7,500 CT equivalents for mobile to 3,500 CT equivalents consistent with required maintenance volumes.
- Section 10: Modified to include acquisition of an existing mobile dental CT scanner service or an existing mobile dental CT scanner.

- Section 11: Added requirements for a dedicated research fixed CT scanner consistent with other CON review standards.
- Section 12: Moved from Section 16.
- Section 13: Removed pilot language and made the requirements for approval of a hospital-based portable CT scanner for initiation, expansion, replacement, and acquisition a permanent part of the standards.
- Section 15: Added requirements for approval of a CT-angio hybrid unit for initiation, replacement, and acquisition.
- Section 17: Added additional requirements for approval of a mobile dental CT scanner service.
- Section 20: Divided requirements into distinct groups consistent with other standards: quality assurance, access to care, and monitoring and reporting.
    - Under subsection (4)(a), clarified language for maintenance volume requirements.
    - Under subsection (7), removed the reference to "pilot" program and updated language.
    - Under subsection (8), added project delivery requirements for CT-angio hybrid units.
- Section 22: Modified table for clarity and added "bundled body scan" with a conversion factor of 3.50 for adults and a conversion factor of 4.00 for pediatric/special needs patients.
- Section 23: Modified for clarity.
- Appendix A: Modified for consistency with other CON review standards.
- Other technical edits.

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

- Section 4: Modified for the CD-9-CM to ICD-10-CM Code translation.
- Appendix E: Added new Appendix for the ICD-9-CM to ICD-10-CM Code translation.
- Other technical edits.

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

- Section 1: Modified for consistency with other CON review standards.
- Section 2: Definitions have been modified, definitions moved to applicable sections if only used in that section, and a new definition has been added for "special care nursery services" or "SCN services."
- Section 5: Moved from previous Section 7.
- Section 6: Moved from previous Section 6.
- Section 7: Moved from previous Section 5.
- Section 9: Added requirements to initiate, acquire, or replace SCN services.
- Section 12: Divided requirements into distinct groups consistent with other standards: quality assurance, access to care, and monitoring and reporting.
    - Under subsection (3), added quality assurance requirements for SCN services.
    - Under subsection (5)(a)(i), added data reporting requirements for SCN services.
- Section 14: Added language to exempt SCN services from comparative review.
- Appendix B: Moved from previous Section 12.

- Other technical edits.

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

- Section 1: Modified for consistency with other CON review standards.
- Section 2: Definitions have been modified and a new definition has been added as follows:
    - "Hospital" means a health facility licensed under part 215 of the code.
- Section 7: Divided requirements into distinct groups consistent with other standards: quality assurance, access to care, and monitoring and reporting.
    - Under subsection (2)(b), reduced the minimum number of cases to be performed by the attending physician from 75 to 50 consistent with the national guidelines.
    - Under subsection (2)(c), added a requirement to participate with the Society of Thoracic Surgeons (STS) National Database and the Michigan Society of Thoracic and Cardiovascular Surgeons (MSTCVS) Quality Collaborative and Database or a designee of the Department that monitors quality and risk adjusted outcomes.
    - Under subsection (4)(a), for consistency, the data that is submitted to the CON Annual Survey will be the same data that is submitted to the STS Database for consistency. The maintenance volume is being reduced from 300 to 150 adult open heart surgical cases a year.
    - Under subsection (4)(d) and (e), added requirements to utilize and report the STS Composite Star Rating System for all procedures.
- Section 8: Modified for clarification.
- Section 9: Modified for clarification.
- Appendix A: Updated utilizing the 2010 Michigan Inpatient Data Base (MIDB).
- Appendix B: Updated utilizing the 2010 Michigan Inpatient Data Base (MIDB).
- Other technical edits.

A second set of revisions to the CON Review Standards for OHS Services include the following and have been implemented:

- Section 2: Definition moved to applicable Appendix.
- Subsection (1)(m): Modified for the ICD-9-CM to ICD-10-CM Code translation.
- Section 8(3): Modified for the CD-9-CM to ICD-10-CM Code translation.
- Section 9(1)(a) and (e), (2)(a) and (c), and (3): Modified for the CD-9-CM to ICD-10-CM Code translation.
- Appendix A: Modified for the CD-9-CM to ICD-10-CM Code translation.
- Appendix B: Modified for the CD-9-CM to ICD-10-CM Code translation.
- Appendix C: Added new Appendix for the ICD-9-CM to ICD-10-CM Code translation.
- Appendix D: Added new Appendix for the ICD-9-CM to ICD-10-CM Code translation.
- Appendix E: Added new Appendix for the ICD-9-CM to ICD-10-CM Code translation.
- Other technical edits.

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

- Section 12(4): Modified for the ICD-9-CM to ICD-10-CM Code translation.

- Appendix D: Added new Appendix for the ICD-9-CM to ICD-10-CM Code translation.
- Other technical edits.

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

- Section 1: Modified for consistency with other CON review standards.
- Section 2: Definitions have been moved to applicable sections if only used in that section.
- Section 3: Modified definition as relocation is a part of replacement.
- Section 4: Modified as relocation is a part of replacement.
- Section 5: Moved from Section 8.
- Section 7: Moved from Section 5.
- Section 9: Divided requirements into distinct groups consistent with other standards: quality assurance, access to care, and monitoring and reporting.
- Section 10: Modified for the ICD-9-CM to ICD-10-CM Code translation.
- Appendix A: Modified for the ICD-9-CM to ICD-10-CM Code translation.
    - Under subsection (1), updated the factor from .94 to 1.09.
    - Modified for clarity.
- Appendix B: Moved from Section 1.
- Appendix D: Added new Appendix for the ICD-9-CM to ICD-10-CM Code translation.
- Other technical edits.

CERTIFICATE OF NEED (CON) COMMISSION BYLAWS

ARTICLE I - PREAMBLE

The Michigan CON Commission (Commission) is created in the Michigan Department of Community Health (the Department) and is established under the Michigan Public Health Code, 1978 PA 368, MCL 333.1101, et seq., as amended (the Code). The Bylaws developed by the Commission remain in effect until amended as provided for in Article X.

ARTICLE II - DEFINITIONS

Unless defined in these Bylaws, the terms used in these Bylaws have the meaning ascribed to them in Parts 201 and 222 of the Code.

ARTICLE III - GENERAL PURPOSE

The duties of the Commission are set forth in Section 22215 of the Code. The Commission exercises its duties to promote all of the following:

A. The availability and accessibility of quality health services at reasonable cost and with reasonable geographic proximity for all people in the state;

B. Appropriate differential consideration of the health care needs of residents in rural counties in ways that do not compromise the quality and affordability of health care services for those residents; and

C. Consideration of the impact of a proposed restriction on the acquisition of or availability of covered clinical services on the quality, accessibility, and cost of health services in this state.

ARTICLE IV - MEMBERSHIP OF THE COMMISSION

A. Size and Composition

The Commission consists of 11 members as designated under Section 22211 of the Code.

B. Term of Office

Commission members will serve a term as set forth in Section 22211(3) of the Code.

ARTICLE V - MEETINGS OF THE COMMISSION

A. Quorum, Voting Procedures, and Proxy Votes

1. Section 22213 of the Code defines a quorum for the Commission. With an 11 member Commission, a quorum is 6 of the 11 members appointed and serving.

2. Final action by the Commission shall be only by affirmative vote of a majority of the Commission members appointed and serving. Any action taken in the absence of a quorum is invalid. If the Commission properly notices a meeting under the Open Meetings Act, but lacks a quorum when it actually convenes, the Commission members in attendance may receive reports and comments from the public or from the Department, ask questions, and comment on matters of interest.

3. Commission members cannot assign a proxy.

B. Compliance with Open Meetings Act

The Commission must adhere to the provisions of the Michigan Open Meetings Act, 1976 PA 267, as amended, MCL 15.261, et seq.

C. Governance under Robert's Rules of Order Revised

The Commission's procedural activities are governed by Robert's Rules of Order Newly Revised if they are consistent with state law and these Bylaws.

D. Regular and Special Meetings

1. In September, the Commission must announce the regular meeting dates for the following year. Special meetings may be called as provided for in Section 22213 of the Code.

2. A regular or special meeting of the Commission may be recessed and reconvened consistent with the provisions of the Michigan Open Meetings Act, 1976 PA 267, as amended, MCL 15.261, et seq.

E. Meeting Attendance

1. Commission members are expected to attend all regular and special meetings except on those occasions where good cause exists.

2. When a Commission member will be unable to attend a regular or special meeting, every effort should be made to give advance notice to the

Department, which must notify the Commission chairperson or vice-chairperson.

3. The Commission chairperson determines whether good cause exists for the absence of a member from a regular or special meeting of the Commission. When the attendance of the chairperson is under question, the responsibility for determining good cause falls to the Commission vice-chairperson.

4. Pursuant to the Code, the Governor may remove a Commission member from office for failure to attend 3 consecutive meetings in a 1-year period. The Commission chairperson must promptly inform the Governor's office (a) if a member fails to attend the statutory minimum number of consecutive meetings in a 1-year period, and (b) indicate whether good cause existed for such absences.

F. Teleconferencing

Commission members may participate in meetings by teleconferencing consistent with the Open Meetings Act (1976 PA 267, as amended, MCL 15.261. et seq). Upon approval of the Chairperson, Commission members may appear at a meeting via electronic device, including speaker phone or interactive television, provided that a quorum is present at the meeting site and all individuals attending the meeting can hear, and can be heard by, the Commissioner(s) attending via electronic device. Commission members participating in meetings by teleconference cannot use teleconferencing to vote but may speak on matters being considered.

G. Agenda and Background Materials

1. In consultation with the Department and other Commission members, the chairperson must set a tentative agenda for each meeting.

2. No later than 7 days before each meeting, the Department must place the tentative agenda on the appropriate section of the Department's Web site.

3. No later than 5 days before each meeting, the Department must deliver the text for any CON review standards for proposed or final actions and relevant background to each Commissioner (using overnight delivery or Email, as necessary) and post it on the appropriate section of the Department's Web site. At the start of a meeting, the Commission, by unanimous approval, may add CON review standards, that meet statutory requirements for proposed or final action, to the agenda.

ARTICLE VI - OFFICERS AND PROCEDURES FOR ELECTING OFFICERS

A. Election of Chairperson and Vice-Chairperson

On an annual basis, the Commission must elect a chairperson and vice-chairperson for a 1-year term not to exceed 3 consecutive terms. The chairperson and vice-chairperson cannot be members of the same major political party.

B. Procedures for Selecting Officers

1. Any Commission member may nominate officers if the member is appointed and serving and attending the meeting where the selection of officers is to occur.

2. Officers are elected by a majority vote by the Commission members appointed and serving.

C. Responsibilities of Officers

1. The chairperson presides over Commission meetings. In the chairperson's absence, the vice-chairperson presides over the Commission meetings. If neither the chairperson nor vice-chairperson is able to preside over any portion of a meeting, the remaining members of the Commission must select a temporary presiding officer.

2. In the chairperson's absence, the vice-chairperson or the temporary presiding officer will perform the duties designated to the chairperson in the Code and these Bylaws.

D. Filling Vacancies in Officers

1. If the office of chairperson becomes vacant for any reason, the vice-chairperson must vacate the vice-chairperson position and serve as the chairperson for the remaining months of the chairperson's 1-year term.

2. If the office of vice-chairperson becomes vacant for any reason, the Commission must elect a new vice-chairperson by an affirmative vote of a majority of those members appointed and serving, and that person will serve the remaining months of the vice-chairperson's term.

3. If the offices of chairperson and vice- chairperson become vacant simultaneously, the Commission must conduct a special election to fill those positions. New officers must be elected by an affirmative vote of a majority of those members appointed and serving and they must serve the remaining months of the chairperson's and vice-chairperson's term.

ARTICLE VII – COMMITTEES

A. Standing New Medical Technology Advisory Committee (NEWTAC)

Composition and duties of the NEWTAC are set forth in Section 22241 of the Code.

B. Standard Advisory Committee (SAC)

If the Commission determines it necessary, it may appoint a SAC to assist in the development of proposed CON review standards in accordance with Section 333.22215(1)(l).

1. The Commission must adopt the duties for a SAC. The duties of the SAC must be defined in a written charge. The written charge to the SAC may be adopted by vote of the Commission, or the Commission may instruct the chairperson to write the charge, consistent with the language adopted by the Commission.

2. The term of any SAC expires 6 months from the first meeting of the SAC or at an earlier date as specified by the Commission.

3. The chairperson appoints the members of a SAC consistent with statutory requirements and the criteria outlined in this subpart.

    a. The Department determines whether a candidate for a SAC meets the following criteria:

        i. The candidate has not served on more than 2 SACs within any 2-year period.

        ii. The candidate is not a lobbyist registered under 1978 PA 472, MCL 4.411 TO 4.431.

        iii. The candidate is not affiliated with a program with a Letter of Intent (LOI) or a pending application in the CON process related to the standard(s) being reviewed.

    b. A SAC consists of a 2/3 majority of experts with professional competence in the subject matter of the proposed standard. The Department determines whether a candidate seeking to be appointed as an expert to a SAC meets the following criteria:

        i. The candidate is a clinician, e.g., doctor, nurse, or other health care professional, who has specific education, training, and experience in the service being considered; or the candidate is a representative of

an organization concerned with licensed health facilities, e.g., administrator or a specialist in the subject matter of the standard being reviewed, who have specific education, training, and experience in the service being considered.

ii. Professional competence demonstrated by relevant professional activity over a majority of the last five years.

c. A SAC includes representatives of health care provider organizations concerned with licensed health facilities or licensed health professions, as well as representatives of organizations concerned with health care consumers, and the purchasers and payers of health care services.

~~d. Only one employee, director, or officer of any one health system, either directly or through the subsidiaries of a system can be appointed as a member of the same SAC. For purposes of these Bylaws, "health system" means facilities where health care is provided and includes without limitation hospitals, nursing homes, county medical care facilities, home health agencies, hospices, out-patient surgical facilities, laboratories, rural health clinics, freestanding surgical units, ambulatory surgical units, and end stage renal disease and dialysis facilities.~~

4. The Commission chairperson appoints the chairperson of a SAC.

C. Members of the NEWTAC and a SAC are subject to the following provisions:

1. Conflicts of interest consistent with Article IX of these Bylaws.

2. Teleconferencing consistent with Article V(F) of these Bylaws.

3. Michigan Open Meetings Act, 1976 PA 267, as amended, MCL 15.261, et seq.

ARTICLE VIII - PROCEDURE AND LEGAL COUNSEL

A. The presiding officer will use the laws of the State, these Bylaws, and Robert's Rules of Order Newly Revised to resolve any question arising concerning procedure at a meeting of the Commission.

B. The Attorney General of the State of Michigan, or the duly designated Assistant Attorney General, serves as legal counsel to the Commission.

ARTICLE IX - STANDARDS OF CONDUCT BY COMMISSION MEMBERS AND CONFLICT OF INTEREST PROVISIONS

A. Commission members are subject to the provisions of:

1. 1968 PA 317, MCL 15.321 to 15.330 (contracts of public servants with public entities);

2. 1973 PA 196, MCL 15.341 to 15.348 (code of ethics for public officers and employees); and

3. 1978 PA 472, MCL 4.411 to 4.431, (lobbyists and lobbying regulation).

B. Definition - Conflict of Interest

1. Under the State Ethics Act, 1973 PA 196, MCL 15.341, et seq, and in accordance with the Advisory Opinion of the State Board of Ethics of November 5, 2004, a conflict of interest for Commission members exists when the individual member has a financial or personal interest in a matter under consideration by the Commission. The personal interest of a Commission member includes the interest of the member's employer, even though the member may not receive monetary or pecuniary remuneration as a result of an adopted CON review standard.

2. A Commission member does not violate the State Ethics Act if the member abstains from deliberating and voting upon the matter in which the member's personal interest is involved.

3. A Commission member may deliberate and vote on matters of general applicability that do not exclusively benefit certain health care facilities or providers who employ the Commission member, even if the matter involves the member's employer or those for whom the member's employer does work.

4. Deliberating includes all discussions of the pertinent subject matter, even before a motion being made.

C. Procedures - Conflict of Interest

1. A Commission member must disclose any potential conflict of interest after the start of a meeting, when the Commission begins to consider a substantive matter, or, where consideration has already commenced, when a conflict or potential conflict of interest becomes apparent to the member.

2. After a meeting is called to order and the agenda reviewed, the chairperson must inquire whether any Commission member has a conflict or potential conflict of interest with regard to any matters on the agenda.

3. A Commission member who is disqualified from deliberating and voting on a matter under consideration due to a conflict of interest may not be counted to establish a quorum regarding that particular matter.

4. Where a Commission member has not discerned any conflict of interest, any other Commission member may raise a concern whether another member has a conflict of interest on a matter. If a second member joins in the concern, the Commission must discuss and vote on whether the member has a conflict of interest before continuing discussion or taking any action on the matter under consideration. The question of conflict of interest is settled by an affirmative vote of a majority of those Commission members appointed and serving, excluding the member or members in question.

5. The minutes of the meeting must reflect when a conflict of interest had been determined and that an abstention from deliberation and voting had occurred.

ARTICLE X - AMENDMENT OF BYLAWS

A. At a regular or special meeting, a majority of Commission members appointed and serving may propose an amendment to these Bylaws. Any proposal by the Commission to amend these Bylaws must be made at least 30 days in advance of the meeting where final action regarding the amendment is taken.

B. Any Commission member may propose an amendment to these Bylaws. Any proposal by a Commission member to amend these Bylaws must be presented to the Commission and the Department, in writing, at least 30 days in advance of the meeting where final action regarding the amendment is taken.

C. The Department may propose an amendment to these Bylaws. Any proposal by the Department to amend these Bylaws must be presented to the Commission, in writing, at least 30 days in advance of the meeting where final action regarding the amendment is taken.

D. Any amendments to these Bylaws become effective on the date the Commission takes final action to approve the amendment or on a later date if specified in the amendment.

E. Upon adoption of any amendment to these Bylaws, the Department must provide the Commission members with a copy of the updated Bylaws.

F. These Bylaws supercede and replace the Bylaws approved and amended by the Commission on March 25, 2010.

CERTIFICATE OF NEED
3rd Quarter Compliance Report to the CON Commission
October 1, 2013 through September 30, 2014 (FY 2014)

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

MCL 333.22247

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

(2) If the department determines that the recipient of a certificate of need under this part is not in compliance with the terms of the certificate of need or that a person is in violation of this part or the rules promulgated under this part, the department shall do 1 or more of the following:
(a) Revoke or suspend the certificate of need.
(b) Impose a civil fine of not more than the amount of the billings for the services provided in violation of this part.
(c) Take any action authorized under this article for a violation of this article or a rule promulgated under this article, including, but not limited to, issuance of a compliance order under section 20162(5), whether or not the person is licensed under this article.
(d) Request enforcement action under section 22253.
(e) Take any other enforcement action authorized by this code.
(f) Publicize or report the violation or enforcement action, or both, to any person.
(g) Take any other action as determined appropriate by the department.

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

Activity Report

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

Activity	3rd Quarter	Year-to-Date
Approved projects requiring 1-year follow up	86	256
Approved projects contacted on or before anniversary date	59	163
Approved projects completed on or before 1-year follow up	68%	
CON approvals expired	33	74
Total follow up correspondence sent	312	772
Total approved projects still ongoing	317	

Compliance: In accordance with Section 22247 and Rule 9419, the Department performs compliance checks on approved and operational Certificates of Need to determine if projects have been implemented, or if other applicable requirements have been met, in accordance with Part 222 of the Code.

The Department has taken the following actions:

- After a statewide review of the Open Heart Surgery data based on the 2010 Annual Survey, the Department opened 6 compliance investigations of Open Heart Surgery programs not meeting the approved volume requirement. The Department has completed collection of information and investigation of the same. To date, the Department has meet with 3 of the 6 hospitals and has upcoming meetings to finish the meeting phase. After completing this, the Department will determine compliance remedies and draft compliance orders or settlement agreements.

- After a statewide review of the Psychiatric Beds and Services data based on the 2010 Annual Survey, the Department opened 14 compliance investigations of adult and child/adolescent psychiatric programs not meeting the approved occupancy rates. The Department has completed collection of information and investigation of the same. The Department has closed 4 investigations based on more recent data and updated information. The Department has conducted meetings with the remaining 10 psychiatric hospitals (10 adult programs and 1 child/adolescent program) and has determined proposed compliance actions. The Department is working to finalize settlement agreements with the 10 programs to resolve these investigations.

- Clarkston MRI – This facility entered into a renewal lease for the fixed MRI unit without CON approval. The facility was required to correct the issue within an active CON and paid a civil fine of $5,500.

Source: Certificate of Need Evaluation Section, Michigan Department of Community Health.

CERTIFICATE OF NEED

3rd Quarter Program Activity Report to the CON Commission

October 1, 2013 through September 30, 2014 (FY 2014)

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

Measures

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

Activity	3rd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	84	N/A	233	N/A
Letters of Intent Processed within 15 days	84	100%	232	99%
Letters of Intent Processed Online	84	100%	233	100%

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

Activity	3rd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	59	N/A	175	N/A
Applications Processed within 15 Days	59	100%	175	100%
Applications Incomplete/More Information Needed	49	83%	130	74%
Applications Filed Online*	57	100%	161	100%
Application Fees Received Online*	13	23%	41	23%

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

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

Activity	3rd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	17	100%	93	100%
Substantive Applications	26	100%	91	100%
Comparative Applications	0	100%	4	100%

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

Measures – continued

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

Activity	3rd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Emergency Applications Received	0	N/A	0	N/A
Decisions Issued within 10 workings Days	0	N/A	0	N/A

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

Activity	3rd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	13	100%	43	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	3rd Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	3rd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	39	N/A	109	N/A
FOIA Requests Processed on Time	39	100%	105	96%
Number of Applications Viewed Onsite	4	N/A	5	N/A

FOIA – Freedom of Information Act.

Source: Certificate of Need Evaluation Section, Michigan Department of Community Health.

CERTIFICATE OF NEED LEGAL ACTION

(09.17.14)

Case Name	Date Opened	Case Description	Status
Medilodge of Oxford, et al v MDCH, et al Michigan Supreme Court No. 148212*Oakland – Compare Group #95-0217* Includes: *Medilodge of Oxford – CON App # 11-0045* *Medilodge of Clarkston – CON App # 11-0043* *Medilodge of Square Lk – CON App # 11-0041* *Regency on the Lk – CON App # 11-0033* *Manor of Farm. Hills – CON App # 11-0024* *Bloomfield Orchard – CON App # 11-0028* *Sen. Com. Of Auburn Hills – CON App # 11-0023* *Sen. Com. Of Prov. Pk. – CON App # 11-0022*	04/02/13	Application for Leave to Appeal the Circuit Court's 3/12/13 order affirming the Department's decision and dismissing the appeal.	On November 1, 2013 the Court of Appeals issued its Order denying the application for lack of merit. On December 9, 2013, the Medilodge entities filed an application for leave to appeal to the Michigan Supreme Court. On May 27, 2014 the Supreme Court denied Medilodge's Application for Leave to Appeal. This case is closed and the Department's denial is affirmed.

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2013												2014											
	J*	F	M*	A	M	J*	J	A	S*	O	N	D*	J*	F	M*	A	M	J*	J	A	S*	O	N	D*
Bone Marrow Transplantation (BMT) Services													• D	•	• R —	• P	•	• ▲F				PC		
Cardiac Catheterization Services**									•	• PC	•	• R1 —	• R P A	• S	• ▲F S	• S	• S	▮	▮	▮	▮	▮	▮	▮
Computed Tomography (CT) Scanner Services	•R	•	•	•	•	•	•	•	•	•	•	• R —	• P	•	• ▲F			• R —	• P	•	• ▲F			
Heart/Lung and Liver Transplantation Services																						PC		
Hospital Beds									•	• PC	•	• R1 —	• R P A	•	• ▲F R	•	•	• R	•	•	• R —	• P	•	• ▲F
Magnetic Resonance Imaging (MRI) Services																		• R —	• P	•	• ▲F	PC		
Megavoltage Radiation Therapy (MRT) Services/Units**										• PC	•	•	• R A	• S	• S	• S	• S	• S	▮	▮	▮	▮	▮	▮
Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services																		• R —	• P	•	• ▲F			
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	•R	•	•S	•S	•S	•S	•	•	•	•	•	•	•	•	•	•	•	R —	P	•	F▲			
Positron Emission Tomography (PET) Scanner Services										• PC	•	• R1 —	• R P A	•	• ▲F	•	•	•	•	•	•	•	•	R —
Psychiatric Beds and Services																						PC		
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	•R	•	•	•	•	•	•	•	• R	•	•	• R1 —	• P	•	• ▲F			• R —	• P	•	• ▲F			
New Medical Technology Standing Committee	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M
Commission & Department Responsibilities			M			M			M			M	M			M			M			M		
2-year Report to Joint Legislative Committee (JLC) – 1/1/15																			D					R

KEY

▬	-	Receipt of proposed standards/documents, proposed Commission action
*	-	Commission meeting
▉	-	Staff work/Standard advisory committee meetings
▲	-	Consider Public/Legislative comment
**	-	Current in-process standard advisory committee or Informal Workgroup
•		Staff work/Informal Workgroup/Commission Liaison Work/Standing Committee Work
[1]		ICD-10 Translation

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

For Approval September 25, 2014

Updated September 15, 2014

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 Community Health, Office of Health Policy and Innovation, Planning and Access to Care Section, 7th Floor Capitol View Bldg., 201 Townsend St., Lansing, MI 48913, 517-335-6708, **www.michigan.gov/con**.

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

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	June 2, 2014	2016
Bone Marrow Transplantation Services	March 22, 2013	2015
Cardiac Catheterization Services	June 2, 2014	2017
Computed Tomography (CT) Scanner Services	June 2, 2014	2016
Heart/Lung and Liver Transplantation Services	September 28, 2012	2015
Hospital Beds	June 2, 2014	2017
Magnetic Resonance Imaging (MRI) Services	September 18, 2013	2015
Megavoltage Radiation Therapy (MRT) Services/Units	May 24, 2013	2017
Neonatal Intensive Care Services/Beds (NICU)	March 3, 2014	2016
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	March 11, 2011	2016
Open Heart Surgery Services	June 2, 2014	2017
Positron Emission Tomography (PET) Scanner Services	June 2, 2014	2017
Psychiatric Beds and Services	March 22, 2013	2015
Surgical Services	February 27, 2012	2017
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	June 2, 2014	2016

*Pursuant to MCL 333.22215 (1)(m): "In addition to subdivision (b), review and, if necessary, revise each set of certificate of need review standards at least every 3 years."

**A Public Comment Period will be held in October prior to the review year to determine what, if any, changes need to be made for each standard scheduled for review. If it is determined that changes are necessary, then the standards can be deferred to a standard advisory committee (SAC), workgroup, or the Department for further review and recommendation to the CON Commission. If no changes are determined, then the standards are scheduled for review in another three years.

CERTIFICATE OF NEED LEGAL ACTION

(09.17.14)

Case Name	Date Opened	Case Description	Status
Pontiac Osteopathic Hospital dba McLaren Oakland Oakland County Circuit Court Includes: CON App # 12-0024 and 12-0025	6/20/13	Appeal of the MDCH Director's final decision.	On December 20, 2013, the Oakland County Circuit Court affirmed the Department's denial of McLaren's application for CON. On January 13, 2014, McLaren filed an Application for Leave to Appeal in the Court of Appeals that was denied for lack of merit. On July 22, 2014, McLaren filed an Application for Leave to Appeal in the Michigan Supreme Court. Both parties have filed briefs and we are awaiting a decision.
Case Name	Date Opened	Case Description	Status
Medilodge of Monroe Michigan Administrative Hearing System Includes: CON App # 14-0015	9/5/14	Administrative appeal of proposed decision denying application for new nursing home beds based on results of comparative review by the Department.	Pre-hearing conference scheduled for September 25, 2014.