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

Thursday, September 17, 2020

Zoom Meeting

APPROVED MINUTES

I. Call to Order & Introductions

Chairperson Falahee called the meeting to order at 9:33 a.m.

A. Members Present:

James B. Falahee, Jr., JD, Chairperson
Thomas Mittelbrun, Vice-Chairperson
Lindsey Dood (joined at 10:09 a.m.)
Amy Engelhardt-Kalbfleisch, DO
Debra Guido-Allen, RN
Ashok Kondur, MD
Melanie K. Lalonde
Lorissa MacAllister, PhD
Amy McKenzie, MD
Melisa J. Oca, MD

B. Members Absent:

Justin B. Dimick, MD

C. Department of Attorney General Staff:

Becky Berels

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

Tulika Bhattacharya
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Introduction of Commissioners and Staff

Chairperson Falahee thanked past Commissioners Stewart Wang, Tressa Gardner, Denise Brooks-Williams, Robert Hughes, and Assistant Attorney General Carl Hammaker for their assistance with the Commission over the years. He asked the new Commissioners and Becky Berels to introduce themselves.

III. Review of Agenda

Motion by Commissioner Guido-Allen, seconded by Commissioner McKenzie to approve the agenda as modified by moving item XV to item IX. Motion carried.

IV. Declaration of Conflicts of Interests

None.

V. Review of Minutes of June 18, 2020

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

VI. Computed Tomography (CT) Scanner Services – Public Hearing Summary

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

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Mittlebrun, seconded by Commissioner McKenzie to take final action on the language (Attachment B) as presented and forward to the Joint Legislative Committee (JLC) and Governor for the 45-day review period. Motion carried.

VII. Neonatal Intensive Care Services/Beds (NICU) Workgroup – Final Report and Draft Language

NICU Workgroup Chairperson Melisa Oca, MD provided the report and presentation (Attachments C and D).

A. Public Comment

None.

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Mittlebrun, seconded by Commissioner Guido-Allen to take proposed action on the language (Attachment E) as presented and move forward to Public Hearing and to the JLC. Motion carried.

VIII. Nursing Home/Hospital Long-Term Care Unit Beds (NH/HLTCU) Standards Advisory Committee (SAC) – Final Report and Draft Language

NH/HLTCU SAC Chairperson Donald Haney provided the report (Attachment F).

A. Public Comment

None.

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Lalonde, seconded by Commissioner Kondur to take proposed action on the language (Attachment G) as presented and forward to Public Hearing and to the JLC. Motion carried.

XV. Public Comment

1. Sean Gehle, Trinity Health (Attachment H)

2. Brett Jackson, Economic Alliance of Michigan (EAM)

Commission discussion followed.

Motion by Commissioner McKenzie, seconded by Commissioner Kondur to add the two charges from Mr. Casalou as well as the additional charge from EAM are taken up by the chair and the vice chair to work with the Department to develop the language related to adding these charges to the SAC. Motion carried.

IX. Review Draft of CON Commission Biennial Report to JLC

Ms. Rogers provided an overview of the biennial report (Attachment I).

X. Cardiac Catheterization Services SAC *(Written Interim Report Only)*

Chairperson Falahee mentioned the written report provided by Cardiac Catheterization Services SAC Chairperson Ryan Madder (Attachment J).

XI. Legislative Update

Chairperson Falahee provided an update.

XII. Administrative Update

A. Planning & Access to Care Section Update

Ms. Nagel provided an update.

B. CON Evaluation Section Update

Ms. Bhattacharya provided an update on the following items:

1. Compliance Report (Attachment K)
2. Quarterly Performance Measures (Attachment L)
3. Statewide Compliance Review for Air Ambulance (Attachment M)
4. Intersocietal Accreditation Commission (IAC) is approved for accreditation for cardiac catheterization services.

XIII. Legal Activity Report

Ms. Berels provided an update on the CON legal activity (Attachment N).

XIV. Future Meeting Dates: December 10, 2020, January 28, 2021, March 18, 2021, June 17, 2021, September 16, 2021, and December 9, 2021

XVI. Review of Commission Work Plan

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

A. Commission Discussion

None.

B. Commission Action

Motion by Commissioner Mittlebrun, seconded by Commissioner Guido-Allen to accept the Work Plan as presented with updates from today's meeting. Motion carried.

XVII. Adjournment

Motion by Commissioner Mittlebrun, seconded by Commissioner Guido-Allen to adjourn the meeting at 10:56 a.m. Motion Carried.

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

Date: August 10, 2020

TO: The Certificate of Need (CON) Commission

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

RE: Summary of Public Hearing Comments on Computed Tomography (CT) Scanner Services Standards

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the CT Standards at its June 28, 2020 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed NH/HLTCU Standards on July 30, 2020. Written testimony was accepted for an additional seven days after the hearing. Testimony was received from three organizations.

Written Testimony:

1.) Alisha Cottrell – Ascension Michigan
- Supports the proposed language.

2.) Barbara Bressack – Henry Ford Health System (HFHS)
- Supports the proposed language.

3.) Ron Lewis – Spectrum Health
- Supports the proposed language.

Department Recommendation:

The Department supports the language as presented at the June 18, 2020 CON Commission meeting.

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 16.

(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, non-diagnostic, intra-operative guidance tomographic units, and dental CT scanners that generate a peak power of 5 kilowatts or less as certified by the manufacturer and are specifically designed to generate CT images to facilitate dental procedures by a licensed dentist under the practice of dentistry.

(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) "CT-GUIDED ABLATION" MEANS ANY INVASIVE PROCEDURE PERFORMED IN A CT SCANNER REQUIRING CT GUIDANCE OF A NEEDLE OR OTHER DEVICE TO TREAT A TUMOR.

(n) "CT-GUIDED NON-ABLATION PROCEDURE" MEANS ANY INVASIVE PROCEDURE, REQUIRING CT GUIDANCE, PERFORMED IN THE CT SCANNER OTHER THAN CT-GUIDED ABLATIONS.

(o) "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~~p) "Department" means the Michigan Department of Health and Human Services (MDHHS).

(~~o~~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.

(~~p~~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.

(~~q~~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.

(~~r~~t) "Existing CT scanner" means a CON-approved and operational CT scanner used to provide CT scanner services.

(~~s~~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.

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

(~~u~~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.

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

(~~w~~y) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996.

(~~x~~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.

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

(~~z~~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.

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

(~~bb~~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.

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

(~~dd~~ff) "Pediatric patient" means any patient less than 18 years of age.

(~~ee~~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.

(~~ff~~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 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 expand an existing CT scanner service

Sec. 4. An applicant proposing to expand an existing CT scanner service, other than 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 8, 9, and 12, 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 12 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 5. Requirements for approval for applicants proposing to replace an existing CT scanner

Sec. 5. An applicant proposing to replace an existing CT scanner or service, other than 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 unless the applicant meets the requirement in subsection (c)(ii) or (iii).

(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 unless one of the following requirements are met:

(i) An applicant meets all of the requirements of Section 3(1);

(ii) the owner of the building where the site is located has incurred a filing for bankruptcy under Chapter Seven (7) within the last three years;
(iii) the ownership of the building where the site is located has changed within 24 months of the date of the service being operational; or
(iv) the CT service being replaced is part of the replacement of an entire hospital to a new geographic site and has only one (1) CT unit.
(d) The applicant agrees to operate the CT scanner service in accordance with all applicable project delivery requirements set forth in Section 14 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 14 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 6. Requirements for approval for applicants proposing to acquire an existing CT scanner service or an existing CT scanner(s)

Sec. 6. An applicant proposing to acquire an existing fixed or mobile CT scanner service, other than a hospital-based portable CT scanner service, shall demonstrate the following, as applicable:

(1) The applicant shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs if the proposed project meets one of the following:
(a) It is the first acquisition of the existing fixed or mobile CT scanner service for which a final decision has not been issued after June 4, 2004.
(b) The existing fixed or mobile CT scanner service is owned by, is under common control of, or has a common parent as the applicant, and the CT scanner service shall remain at the same site.

(2) 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:
(a) 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) or meets the requirements of Section 6(1)(b).
(b) 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, unless an applicant meets the requirements of Section 6(1)(b).

(3) 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.

(4) The CT scanner service shall be operating at the applicable volume requirements set forth in Section 14 of these standards in the second 12 months after the date the service is acquired, and annually thereafter.

Section 7. Requirements for a dedicated research fixed CT scanner

Sec. 7. 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 8. Requirements for approval of a hospital-based portable CT scanner for initiation, expansion, replacement, and acquisition

Sec. 8. 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 14 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 9. Requirements for approval of a PET/CT hybrid for initiation, expansion, replacement, and acquisition

Sec. 9. 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 14 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 10. Requirements for approval of a CT-angio hybrid unit for initiation, replacement, and acquisition

Sec. 10. 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 11. Additional requirements for approval of a mobile CT scanner service

Sec. 11. (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 4 have been met.

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

Section 12. Requirements for approval of an applicant proposing to establish dedicated pediatric CT Scanner

Sec. 12. (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 13. Requirements for Medicaid participation

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 and terms of approval for all applicants

Sec. 14. 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 (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 shall be made available 24 hours a day for emergency patients if the facility operates an emergency room that provides 24-hour emergency care services ~~as~~ AND authorized by the local medical control authority to receive ambulance runs.

(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 12 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 AS FOLLOWS FOR THE SECOND 12-MONTH PERIOD AFTER BEGINNING OPERATION OF THE CT SCANNER, AND ANNUALLY THEREAFTER, EXCEPT FOR THOSE SCANNERS EXEMPT UNDER APPLICABLE SECTIONS:

(i) ~~at an~~ An average of 7,500 CT equivalents ~~scanner~~ per fixed scanner PER YEAR UNLESS ONE OF THE FOLLOWING HAS BEEN MET:

(A) 5,000 CT EQUIVALENTS PER FIXED SCANNER PER YEAR FOR CT SERVICES WITH ONE FIXED SCANNER.

(B) 2,500 CT EQUIVALENTS PER FIXED SCANNER PER YEAR FOR CT SERVICES WITH ONE FIXED SCANNER LOCATED OUTSIDE THE 20-MILE RADIUS FROM THE NEXT CLOSEST FIXED CT SERVICE.

(C) A HOSPITAL, WITH ONE FIXED SCANNER, LICENSED UNDER PART 215 OF THE CODE THAT OPERATES AN EMERGENCY ROOM THAT PROVIDES 24-HOUR EMERGENCY CARE SERVICES AND AUTHORIZED BY THE LOCAL MEDICAL CONTROL AUTHORITY TO RECEIVE AMBULANCE RUNS SHALL NOT HAVE A MINIMUM ANNUAL VOLUME REQUIREMENT FOR PURPOSES OF THIS SECTION.

(D) A FREESTANDING SURGICAL OUTPATIENT FACILITY (FSOF), WITH ONE FIXED SCANNER, LICENSED UNDER PART 208 OF THE CODE THAT OPERATES AN EMERGENCY ROOM THAT PROVIDES 24-HOUR EMERGENCY CARE SERVICES AND AUTHORIZED BY THE LOCAL MEDICAL CONTROL AUTHORITY TO RECEIVE AMBULANCE RUNS SHALL NOT HAVE A MINIMUM ANNUAL VOLUME REQUIREMENT FOR PURPOSES OF THIS SECTION.

(E) AN OFF-CAMPUS EMERGENCY DEPARTMENT OF A HOSPITAL, LICENSED UNDER PART 215 OF THE CODE, WITH ONE FIXED SCANNER, THAT HAS OBTAINED PROVIDER-BASED STATUS UNDER 42 CFR 413.65, THAT IS AVAILABLE FOR TREATING EMERGENCY PATIENTS 24 HOURS A DAY, 7 DAYS A WEEK, AND AUTHORIZED BY THE LOCAL MEDICAL CONTROL AUTHORITY TO RECEIVE AMBULANCE RUNS SHALL NOT HAVE A MINIMUM ANNUAL VOLUME REQUIREMENT FOR PURPOSES OF THIS SECTION.

(ii) ~~and 3~~1,500 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.

(5) An applicant approved under Section 8 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 8.

(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

(6) An applicant approved under Section 10 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

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

Section 15. Project delivery requirements and additional terms of approval for applicants involving mobile CT scanners

Sec. 15. (1) In addition to the provisions of Section 14, 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 Department 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 14(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 16. Determination of CT Equivalents

Sec. 16. CT equivalents shall be calculated as follows:

(~~a~~1) 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~~2) 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~~3) 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~~4) THE WEIGHTING IN TABLE 1 IS BASED ON TYPICAL TREATMENT TIMES AND ASSUMES THE CONVERSION FACTOR EQUALS APPROXIMATELY 15 MINUTES OF TIME ON THE CT UNIT.

(5) 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
Adult Patient					
Head Scans w/o Contrast	_____	X	1.00	=	_____
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	=	_____
CT-GUIDED NON-ABLATION					
PROCEDURE	_____	X	4.00	=	_____
CT-GUIDED ABLATION	_____	X	8.00	=	_____
Pediatric/Special Needs Patient					
Head scans w/o Contrast	_____	x	1.25	=	_____
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	=	_____
CT-GUIDED NON-ABLATION					
PROCEDURE	_____	X	4.25	=	_____
CT-GUIDED ABLATION	_____	X	8.25	=	_____
Total CT Equivalents					_____

Section 17. Documentation of projections

Sec. 17. An applicant required to project volumes under Section 3 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 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. 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 18. Effect on prior CON review standards; comparative reviews

Sec. 18. (1) These CON review standards supersede and replace the CON Review Standards for Computed Tomography Scanner Services approved by the CON Commission on September ~~25~~21, ~~2014~~ 2016 and effective on December ~~22~~9, ~~2014~~2016.

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674 (2) Projects reviewed under these standards shall not be subject to comparative review.
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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	Gogebic	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Montmorency	Schoolcraft
Emmet	Newaygo	Tuscola
Gladwin	Oceana	

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

Neonatal Intensive Care Unit (NICU) and Special Care Nursery (SCN) Services Workgroup Final Report

The NICU/ SCN services workgroup, as charged by the Certificate of Need Commission, has held the following meetings to date : December 12, 2019, January 9, 2020 and via teleconference (due to Covid 19 meeting restrictions) March 12, May 14, June 4, July 9 and August 12, 2020. All meetings began at 9:30 am and concluded at 11:30 pm..

We have had active participation from all the major health systems across the state listed below:

St. Joseph Mercy Ann Arbor
Henry Ford Health System
Arbor Advisors
RWC Advocacy
Covenant
Mercy Health St. Mary's Grand Rapids
Dexter Area Fire Department
MidMichigan Health
Hurley Medical Center
MEDNAX
Blue Cross Blue Shield of Michigan
Arbor Advisors
RWC Advocacy
Dexter Area Fire Department
Michigan Department of Health and Human Services
Blue Cross Blue Shield of Michigan
Beaumont Health
University of Michigan
Sparrow Health
Munson Health
Spectrum Health
Ascension Michigan
Children's Hospital of Michigan
McLaren Health
Blue Cross Blue Shield of Michigan
Henry Ford Health System
Mercy Health Grand Rapids
Covenant

Discussion regarding each of the charges are summarized below:

Charge 1: Should High Flow Nasal Cannula (HFNC) be included as accepted services for SCNs:

To address this charge the workgroup developed a survey to assess the current use of HFNC (>/= 2L/ min) in SCNs across the state, complications of the use, and need for transfer of patients to higher level of care. The overall trend was increasing use of HFNC in SCNs without an increase in complications (pneumothorax). The need for transfer to a higher level of care for infants requiring greater than 24 hours of HFNC was 21%. Discussion regarding the limit of 24 hour use of CPAP in SCNs evolved upon review of the American Academy of Pediatrics (AAP) 2012 guidelines on Levels of Neonatal Care. The workgroup concluded that a time limit should not be placed on either HFNC or CPAP.

The workgroup recommends:
HFNC is an accepted service for SCNs

Charge 2: Should Neonatal Abstinence Syndrome (NAS) be included as accepted services for SCNs:

With the rise of opioid use and subsequent effects on newborns, the need to treat and monitor infants with NAS has greatly increased around the state. Many infants are born in rural areas and require transfer to higher level of care, separating mom and infant, and incurring higher costs of medical care. The workgroup also recognized that there are well-born Level 1 nurseries in rural areas that currently provide exceptional care for NAS newborns and the impact of adding this accepted service to SCNs would prohibited them from doing so if this language was added. With concerns raised that this language would ultimately limit access to this service unnecessarily, the workgroup agreed to not include NAS language for the SCN definition so that all nurseries with the appropriate capabilities, equipment, and staff, will continue to be allowed to provide NAS treatment.

The workgroup recommends:
Not include NAS language for the SCN definition of services

Charge 3: In section 12(2) determine if telemedicine can be used as an acceptable replacement for on-site services:

Telemedicine is already in active use amongst community NICUs across the state and country, providing neonatal/pediatric sub-specialty support. These include but are not limited to cardiology, ophthalmology, surgery and neurosurgery (on-site services). Draft language has been proposed and accepted to include the use of telemedicine as a replacement for on-site consultative needs of NICU. The group also discussed the importance of neonatal telemedicine that can provide supportive services to both SCNs and well born nurseries to avoid maternal -infant separation and costly transfers.

The workgroup recommends:
Telemedicine, as defined by the Legislature, is an acceptable replacement for onsite NICU consultative services.

Charge 4: Occupancy requirements and high occupancy provisions for NICU:

A subgroup was formed to explore a new high occupancy provision in line with the other high-occupancy standards (i.e hospital, nursing home and psych bed standards). The current bed methodology to expand NICU services is dependent upon transfers from other NICUs. The new bed methodology does not depend on transfers, and is in-line with methodology for other high occupancy standards. This will provide NICUs that have a high delivery rate (and may not have a high transfer rate) to expand services appropriately.

The workgroup recommends:
Existing NICU beds operating at an occupancy rate of 80% or above for the previous consecutive 24 months may be approved for additional beds (using bed methodology calculations as defined in NICU draft standards) to reduce the occupancy rate to 70%

Charge 5: Minimum NICU size exception for rural or micropolitan counties:

A subgroup was formed to address modification of NICU size. The current standards require a minimum size of 15 NICU beds. National studies consistently find a strong correlation between volume and quality in NICU services, highlighting regionalization of NICU services and urge

against proliferation of smaller NICUs in an attempt to increase access. No evidence was found to support concerns with access to NICUs across Michigan. There are 3 facilities in the State currently with fewer than 15 NICU beds; however they have in-house SCN beds which allows for flexing capacity as needed. Though no specific studies were found to address a minimum sized NICU from a financial sustainability, the experienced subgroup members agreed that 15 beds is an appropriate number to ensure financial sustainability.

The workgroup recommends:
No exception to a NICU minimum size for rural/ micropolitan counties.

Charge 6: Definition of NICU Services found in Section 2
Charge 7: Consideration of other technical changes from the Department, e.g., updates or modifications consistent with other CON review standards and the Michigan Public Health Code:

The workgroup discussed the importance of understanding the definition of NICU/SCN/Well Newborn services and reviewed the AAP guidelines published in Pediatrics 2012: Levels of Neonatal Care. The workgroup and Department agree the Levels of Neonatal Care standards (NICU/SCN/Well newborn services) should be in line with AAP guidelines; the interpretation of these guidelines led to vigorous discussion throughout the meetings. At the final workgroup meeting on August 12, 2020, the workgroup participants and Department agreed to all draft language presented in the 2020 Draft CON Standards for NICU and Special Newborn Nursing Services.

SUMMARY/HIGHLIGHTS

HFNC is an accepted service for SCN
CPAP is an accepted service for SCN (no time limit)
NAS services not defined to any Neonatal Level of Care
Telemedicine (as defined by the Legislature) is an acceptable replacement for on-site consultative services
Bed methodology re-defined for High Occupancy Provisions
No exception to a NICU minimum size for rural/ micropolitan counties.

NICU/SCN Workgroup Final Report

September 17, 2020

Arbor Advisors
Ascension Michigan
Beaumont Health
Blue Cross Blue Shield of Michigan
Children's Hospital of Michigan
Covenant Health Care
Henry Ford Health System
Hurley Medical Center
McLaren Health
Michigan Department of Health and Human Services
Mercy Health St. Mary's
MidMichigan Health
Munson Health
RWC Advocacy
Sparrow Health
Spectrum Health
St. Joseph Mercy Ann Arbor
University of Michigan

Charge 1: Should High Flow Nasal Cannnula (HFNC) be included as acceptable services for Special Care Nursery (SCN)

Survey conducted to assess current use, complications and need for transfer

Results: Increasing use of HFNC across SCNs

No increase in complications (pneumothorax)

1/5 of infants requiring > 24 hours of HFNC were transferred

Charge 1: Workgroup recommends High Flow Nasal Cannnula (HFNC) be included as acceptable services for Special Care Nurserys (SCN)

Charge 2: Should Neonatal Abstinence Syndrome (NAS) be included as accepted services for Special Care Nursery (SCN)

Opiod use and subsequent effects on newborns requiring monitoring and treatment has greatly increased.

Well born Nurseries (Level 1) in rural areas currently provide exceptional care for NAS newborns

Language added to include NAS as accepted service for SCN would prohibit well born nurseries from continuing their care, limiting access and incur increasing health care costs

Charge 2: Workgroup recommends NOT to include Neonatal Abstinence Syndrome (NAS) as accepted services for Special Care Nursery (SCN)

Charge 3: In section 12(2) determine if telemedicine can be used as an acceptable replacement for on-site services

Telemedicine actively used amongst community NICUs across the state and country providing neonatal/pediatric subspecialty support for Cardiology, Opthalmology, Surgery and Neurosurgery (on-site services)

Use of telemedicine for subspecialty support is consistent with AAP 2012 guidelines for Levels of Neonatal Care

Importance of Neonatal Telemedicine to provide supportive services to both SCN and Well Born Nurseries to avoid maternal-infant separation and costly transfers

Charge 3: Workgroup recommends Telemedicine, as defined by the Legislature, is as an acceptable replacement for on-site services

Charge 4: Occupancy requirements and high occupancy provisions for NICU

Sub-group formed to explore new high occupancy provisions that are in-line with other high occupancy standards (i.e. hospital, nursing home and psych bed standards)

Current methodology to expand services dependant on transfers from other NICUs; does NOT provide for NICUs with high delivery rates

New methodology drafted by sub-group is in-line with bed methodology for other high occupancy standards; does not depend on transfers from other NICUs ; does provide for NICUs with high delivery rates to expand appropriately

Charge 4: Workgroup recommends existing NICU beds operating at an occupancy rate of 80% or above for the previous consecutive 24 months may be approved for additional beds (using bed methodology as defined in NICU draft standards Section 7 (2)) to reduce the occupancy rate to 70%

Charge 5: Minimum NICU size exception for rural or micropolitan counties

Current standards require minimum size of 15 NICU beds

Sub-group formed to address modification of NICU size.

National studies find strong correlation between volume and quality in NICU services, highlight regionalization of NICU services, urge against proliferation of smaller units in attempt to increase access. No evidence to support concerns with access to NICUs around the state

Conclusion: 15 beds is an appropriate number to ensure quality of NICU service and financial sustainability

Charge 5: Workgroup recommends no exception to a minimum NICU size for rural or micropolitan counties

Charge 6: Definition of NICU Services found in Section 2
Charge 7: Consideration of other technical changes, updates, modifications consistent with other CON review standards

Important that definition of NICU/SCN/Well born Nursery Services are in line with the AAP guidelines published in Pediatrics 2012: Levels of Neonatal Care

Vigorous discussion surrounding the use of CPAP in SCN - currently limited to 24 hours. Review of AAP guidelines does not place a time limit on use of CPAP; time limit is defined for provision of mechanical ventilation (<24 hours).

Important to include the use of Telemedicine to provide support to SCN for stabilization and care of infants, in addition to its use for sub-specialty consultative services in NICU

Summary of Workgroup Recommendations:

High Flow Nasal Cannula is an accepted service for Special Care Nursery (SCN)

Continuous Positive Airway Pressure is an accepted service for SCN (no time limit)

NAS services are not defined/limited to and Level of Neonatal Care

Telemedicine (as defined by the Legislature) is an acceptable replacement for on-site consultative services; use to provide additional support to all Levels of Neonatal Care

Bed Methodology re-defined for High Occupancy Provisions

No exception to a NICU minimum size for rural/micropolitan counties

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED REVIEW (CON) STANDARDS FOR NEONATAL INTENSIVE CARE SERVICES/BEDS (NICU) 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 Health and Human Services (MDHHS).

(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~~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~~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 services for infants with problems that are expected to resolve rapidly and who would not be anticipated to need subspecialty services on an urgent basis. These services ~~include~~ARE:

(i) ~~Care~~ care for infants born greater than or equal to 32 weeks gestation and/or weighing greater than or equal to 1,500 grams;

(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 AND HIGH FLOW NASAL CANNULA (HFNC); AND

(vi) mechanical ventilation ~~or both~~ for a brief duration (~~not to exceed~~UP TO 24 hours ~~combined~~). FOR BABIES REQUIRING MECHANICAL VENTILATION EXCEEDING 24 HOURS, SCNS SHALL REQUEST TRANSFER TO A NICU BY THE 24TH HOUR OF MECHANICAL VENTILATION. Referral to a higher level of care should ALSO 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.

(w) "TELEMEDICINE" MEANS THE USE OF AN ELECTRONIC MEDIA TO LINK PATIENTS WITH HEALTH CARE PROFESSIONALS IN DIFFERENT LOCATIONS. TO BE CONSIDERED TELEMEDICINE UNDER THIS SECTION, THE HEALTH CARE PROFESSIONAL MUST BE ABLE TO EXAMINE THE PATIENT VIA A HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996, PUBLIC LAW 104-191 COMPLIANT, SECURE INTERACTIVE AUDIO, VIDEO, OR BOTH, TELECOMMUNICATIONS SYSTEM, OR THROUGH THE USE OF STORE AND FORWARD ONLINE MESSAGING.

(x) "Well newborn nursery services" means providing the following services and does not require a certificate of need:

(i) the capability to perform neonatal resuscitation at every delivery;

(ii) evaluate and provide postnatal care for stable term newborn infants;

(iii) stabilize and provide care for infants born at 35 to 37 weeks' gestation who remain physiologically stable; and

(iv) stabilize newborn infants who are ill and those born less than 35 weeks of gestation until they can be transferred to a higher level of care facility.

(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~~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, EXCEPT AN APPLICANT MEETING THE REQUIREMENTS OF SUBSECTION (2), 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 TO EXPAND NICU SERVICES AT A LICENSED SITE BY DESIGNATING ADDITIONAL HOSPITAL BEDS ~~for~~ AS NICU beds in excess of the number determined as needed for the planning year in accordance with Section 3 if an applicant can demonstrate ALL OF THE FOLLOWING SUBSECTIONS ARE MET~~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~~THE PROPOSED NICU BEDS ARE BEING ADDED AT THE EXISTING LICENSED SITE.

(b) The EXISTING NICU BEDS HAVE OPERATED AT AN OCCUPANCY RATE OF 80 PERCENT OR ABOVE FOR THE PREVIOUS, CONSECUTIVE 24 MONTHS BASED ON THE EXISTING SITE'S LICENSED AND APPROVED NICU BED CAPACITY. THE OCCUPANCY RATE SHALL BE CALCULATED AS FOLLOWS:

(i) ~~average annual~~CALCULATE THE 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~~ PROVIDED TO NEONATES IN THE APPLICANT'S EXISTING NICU BEDS FOR THE MOST RECENT, CONSECUTIVE 24 MONTHS FOR WHICH VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT.

(ii) CALCULATE THE TOTAL POSSIBLE PATIENT DAYS BY MULTIPLYING THE EXISTING LICENSED AND APPROVED NICU BEDS BY 730 (OR 731 IF INCLUDING A LEAP YEAR).

(iii) CALCULATE THE OCCUPANCY RATE BY DIVIDING THE NUMBER CALCULATED IN (i) BY THE NUMBER CALCULATED IN (ii).

(c) ~~Apply the ADC determined in accordance with subsection (b) in the following formula: ADC + 2.06 √ADC. The result is the maximum number of beds that may be approved pursuant to this subsection.~~THE NUMBER OF NICU BEDS THAT MAY BE APPROVED PURSUANT TO THIS SUBSECTION SHALL BE THE NUMBER OF NICU BEDS NECESSARY TO REDUCE THE OCCUPANCY RATE FOR THE NICU TO 70 PERCENT. THE NUMBER OF NICU BEDS TO BE ADDED SHALL BE CALCULATED AS FOLLOWS:

(i) DIVIDE THE NUMBER OF PATIENT DAYS CALCULATED IN SUBSECTION (b)(i) BY .70 TO DETERMINE LICENSED NICU BED DAYS AT 70 PERCENT OCCUPANCY.

(ii) DIVIDE THE RESULT OF STEP (c)(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 EXISTING NICU BED DESIGNATIONS AS DOCUMENTED ON THE "DEPARTMENT INVENTORY OF NICU BEDS" FROM THE RESULT OF STEP (c)(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. IF THE RESULT IS LESS THAN 5 BEDS, THE APPLICANT MAY BE APPROVED FOR UP TO 5 BEDS.

(d) A NICU THAT HAS RELOCATED NICU BEDS~~,~~ AFTER THE EFFECTIVE DATE OF THESE STANDARDS~~,~~ SHALL NOT BE APPROVED FOR NICU BEDS UNDER THIS SUBSECTION FOR FIVE YEARS FROM THE EFFECTIVE DATE OF THE RELOCATION OF BEDS.

(e) APPLICANTS PROPOSING TO ADD NICU BEDS UNDER THIS SUBSECTION SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW.

(f) AN APPLICANT PROPOSING TO ADD NICU BEDS SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE BED NEED METHODOLOGY IF THE APPLICATION MEETS ALL OTHER APPLICABLE CON REVIEW STANDARDS, AND THE APPLICANT AGREES AND ASSURES TO COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS.

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~~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 FOR A BRIEF DURATION (UP TO 24 HOURS). FOR BABIES REQUIRING MECHANICAL VENTILATION EXCEEDING 24 HOURS, SCNS SHALL REQUEST TRANSFER TO A NICU BY THE 24TH HOUR OF MECHANICAL VENTILATION~~.~~;

(ii) ~~and/or~~ continuous positive airway pressure AND HFNC ~~for up to 24 hours~~;

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

(~~iii~~iv) 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~~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~~board-certified neonatologist shall serve as the director of neonatal services.

(h) An applicant shall make provisions for ~~on-site~~ physician consultation services EITHER ON-SITE OR BY PREARRANGED CONSULTATIVE AGREEMENTS in at least the following neonatal/pediatric specialties: cardiology, ophthalmology, surgery and neurosurgery. PREARRANGED CONSULTATIVE AGREEMENTS CAN BE PERFORMED BY USING TELEMEDICINE TECHNOLOGY.

(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~~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 FOR A BRIEF DURATION (UP TO 24 HOURS). FOR BABIES REQUIRING MECHANICAL VENTILATION EXEEDING 24 HOURS, SCNS SHALL REQUEST TRANSFER TO A NICU BY THE 24TH HOUR OF MECHANICAL VENTILATION~~.~~;

(ii) ~~and/or~~ continuous positive airway pressure AND HFNC ~~for up to 24 hours~~;

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

(~~iii~~iv) 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 September ~~25~~21, ~~2014~~ 2016 and effective on December ~~22~~9, ~~2014~~2016.

(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

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

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

THORNAPPLE MANOR

Nursing Home and Hospital Long-Term Care Unit
Standards Advisory Committee
Final Report and Recommendations

I am pleased to report that the Standards Advisory Committee (SAC) for the Nursing Home and Hospital Long-Term Care Units (NH/HLTCU) concluded their work on time and has the following final report and recommendations. A sub-committee was formed to do the detail work of reviewing the current methodology along with the proposed methodology changes. The sub-committee looked at seven different models that maintain the current planning areas and factor in both utilization trending by H.S.A. (Health Service Area) and population projections. The population projections are within the current standards for a 3 to 7-year period. The sub-committee worked with the MDHHS CON staff and their consultant Dr. Paul Delamater.

The SAC had six charges from the CON Commission. Our review and recommendations for those charges are;

Charge 1 – The bed need methodology

Recommendation: new methodology

Our recommended new methodology (see attached) incorporates these basic elements: local utilization by planning area, measured against H.S.A. (Health Service Areas) regional trends times the population prediction. The proposed methodology maintained the following elements from the current bed need methodology: the four age-groups, existing planning area geographic boundaries, data derived from the CON Annual Survey report, a 5-year prediction by planning area and an average daily census (ADC) factor of 90%.

Charge 2 –Whether adequate access exists for Medicaid patients

Recommendation: adequate access exists for Medicaid residents

The SAC discussed this charge and agreed that Michigan does have an adequate supply of nursing home and hospital LTC-unit beds to serve the Medicaid population. The workgroup did express concern with services being available for those citizens needing one-on-one monitoring, substance abuse disorders and other severe behavioral issues. These concerns relate to services not capacity within the system.

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Charge 3 – Specialty population beds

Recommendation: no changes recommended from workgroup

The SAC reviewed the special population bed groups for adequate supply based on the department's inventory. The four pools of special beds are: spinal cord injury, behavioral patients, ventilator dependent patients and bariatric patients. Each of these categories have beds available no changes were recommended by the SAC Committee.

Charge 4 – Language changes presented by the Department regarding adding minimum occupancy requirements to Sections 6 and 8.

Recommendation: not supported by SAC, bring language forward to next standards review period

The SAC reviewed the proposed language and a proposal to change the minimum occupancy requirement in both sections to 60%. However, the SAC concluded that due to the pandemic and its impact on occupancy the effects of this change is unknown and recommends that this issue be brought forward to the next review of these standards.

Charge 5 – Language changes presented by the Department regarding technical edits to Section 7.

Recommendation: Some language changes are recommended

The SAC Committee recommends some language changes as noted in the attached. These language changes have been reviewed by the CON staff and by legal counsel.

Charge 6 – Consider any technical changes from the Department, e.g., updates or modifications consistent with other CON review standards and the Michigan Public Health Code.

Recommendation: Some language changes are recommended

The SAC recommends some language changes as noted in the attached. These language changes have been reviewed by the CON staff and by their legal counsel.

I would like to personally thank the CON staff for their efforts and keeping us on track.

I would like to thank Dr. Paul Delamater for his expertise and assistance in vetting the various methodologies and the SAC's final recommendations.

And finally I would like to thank the SAC members and those who served on the sub-committee (listed in bold) they are;

Frank Wronski, Vice-Chairperson – WellBridge Group
Patricia E. Anderson – Health Care Association of Michigan
Renee Beniak – Michigan County Medical Care Facilities Council
Laura Caldwell – Ascension Michigan
Donna Elston – Spectrum Health Continuing Care
Magaret Lightner – Beaumont Health
Deanna Ludlow Mitchell – Leading Age Michigan
Jon A Nowinski, CPA – Lally Group, PC
Salli Pung – Michigan Long Term Care Ombudsman Program – Michigan Elder Justice Initiative
Holli Titus – Employee Benefit Logistics LLC
Laurrie Murphy Knight, MD – Blue Cross Blue Shield of Michigan

Respectfully Submitted,

Donald A Haney, NHA, CMA, MBA
NH-HLTCU Standards Advisory Committee Chair

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval under Part 222 of the Code that involve a) beginning operation of a new nursing home/HLTCU, (b) replacing beds in a nursing home/HLTCU or physically relocating nursing home/HLTCU beds from one licensed site to another geographic location, (c) increasing licensed beds in a nursing home/HLTCU licensed under Part 217 and a HLTCU defined in Section 20106(6), or (d) acquiring a nursing home/HLTCU. Pursuant to the Code, a nursing home/HLTCU is a covered health facility. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

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

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

Section 2. Definitions

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

(a) "Acquisition of an existing nursing home/HLTCU" means the issuance of a new nursing home/HLTCU license as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing licensed and operating nursing home/HLTCU and which does not involve a change in bed capacity of that health facility.

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

(c) "Applicant's cash" means the total unrestricted cash, designated funds, and restricted funds reported by the applicant as the source of funds in the application. If the project includes space lease costs, the applicant's cash includes the contribution designated for the project from the landlord.

(d) "AVERAGE OCCUPANCY RATE" IS CALCULATED AS FOLLOWS:

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

(ii) CALCULATE THE TOTAL LICENSED BED DAYS FOR THE SAME 12-MONTH PERIOD AS IN (i) ABOVE BY MULTIPLYING THE TOTAL LICENSED BEDS AND CON APPROVED BUT NOT YET LICENSED BEDS BY THE TOTAL NUMBER OF DAYS THEY WERE LICENSED OR CON APPROVED BUT NOT YET LICENSED.

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

(~~d~~e) "Base year" means 1987 or the most recent year for which verifiable data collected as part of the Michigan Department of Health and Human Services Annual Survey of Long-Term-Care Facilities or other comparable MDHHS survey instrument are available.

(~~e~~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.

(~~f~~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.

(~~g~~h) "Common ownership or control" means a nursing home, regardless of the state in which it is located, that is owned by, is under common control of, or has a common parent as the applicant nursing home pursuant to the definition of common ownership or control utilized by the Department of Licensing and Regulatory Affairs (LARA), Bureau of Health Care Services.

(~~h~~i) "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~~j) "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~~k) "Department" means the Michigan Department of Health and Human Services (MDHHS).

(~~k~~l) "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~~m) "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~~n) "Health service area" or "HSA" means the geographic area established for a health systems agency pursuant to former Section 1511 of the Public Health Service Act and set forth in Appendix A.

(~~n~~o) "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~~p) "Licensed only facility" means a licensed nursing home that is not certified for Medicare or Medicaid.

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

(~~q~~r) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396g and1396i to 1396u.

(~~r~~s) "New design model" means a nursing home/HLTCU built in accordance with specified design requirements as identified in the applicable sections.

(~~s~~t) "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.

(tu) "Nursing home bed" means a bed in a health facility licensed under Part 217 of the Code or a licensed bed in a hospital long-term-care unit. The term does not include short-term nursing care program beds approved pursuant to Section 22210 of the Code being Section 333.22210 of the Michigan Compiled Laws or beds in health facilities listed in Section 22205(2) of the Code, being Section 333.22205(2) of the Michigan Compiled Laws.

~~(u) "Occupancy rate" means the percentage which expresses the ratio of the actual number of patient days of care provided divided by the total number of patient days. Total patient days is calculated by summing the number of licensed and/or CON approved but not yet licensed beds and multiplying these beds by the number of days that they were licensed and/or CON approved but not yet licensed. This shall include nursing home beds approved from the statewide pool. Occupancy rates shall be calculated using verifiable data from the actual number of patient days of care for 12 continuous months of data from the CON Annual Survey or other comparable MDHHS survey instrument.~~

(v) "Planning area" means the geographic boundaries of each county in Michigan with the exception of: (i) Houghton and Keweenaw counties, which are combined to form one planning area and (ii) Wayne County which is divided into three planning areas. Section 12 identifies the three planning areas in Wayne County and the specific geographic area included in each.

(w) "Planning year" means 1990 or the year in the future, at least three (3) years but no more than seven (7) years, for which nursing home bed needs are developed. The planning year shall be a year for which official population projections, from the Department of Management and Budget or U.S. Census, 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.

(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.

(z) "Renewal of lease" means execution of a lease between the licensee and a real property owner in which the total lease costs exceed the capital expenditure threshold.

(aa) "Replacement bed" means a change in the location of the licensed nursing home/HLTCU, the replacement of a portion of the licensed beds at the same licensed site, or the replacement of a portion of the licensed beds pursuant to the new model design. The nursing home/HLTCU beds will be in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, etc.) within the replacement zone.

(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.

(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 per 1000 population for each corresponding age cohort, established in accord with subsection (1)(b), are posted on the State of Michigan CON web site.

(2) The number of nursing home beds needed in a planning area shall be determined by the following formula:

(a) ~~Determine the population for the planning year for each separate planning area in the age cohorts established in subsection (1)(b).~~

~~(b) Multiply each population age cohort by the corresponding use rate which is posted on the State of Michigan CON web site.~~

~~(c) Sum the patient days resulting from the calculations performed in subsection (b). The resultant figure is the total patient days.~~

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

~~(e) Divide the ADC determined in subsection (d) by 0.90.~~

~~(f) The number determined in subsection (e) represents the number of nursing home beds needed in a planning area for the planning year.~~ FOR EACH HSA AND FOR EACH AGE COHORT ESTABLISHED IN SUBSECTION (1)(b), PERFORM THE FOLLOWING CALCULATIONS:

(i) DETERMINE THE PATIENT DAYS AND POPULATION FOR THE BASE YEAR AND THREE YEARS PRIOR TO THE BASE YEAR.

(ii) DETERMINE THE PATIENT DAY UTILIZATION RATE PER 1000 PEOPLE FOR THE BASE YEAR AND THREE YEARS PRIOR TO THE BASE YEAR BY DIVIDING THE PATIENT DAYS BY THE POPULATION AND MULTIPLYING BY 1000.

(iii) DETERMINE THE AVERAGE YEARLY CHANGE IN THE PATIENT DAY UTILIZATION RATE FOR THE THREE-YEAR PERIOD BY SUBTRACTING THE UTILIZATION RATE IN THE BASE YEAR FROM THE UTILIZATION RATE FROM THREE YEARS PRIOR AND DIVIDING BY THREE.

(iv) MULTIPLY THE AVERAGE YEARLY CHANGE IN THE PATIENT DAY UTILIZATION RATE BY THE NUMBER OF YEARS BETWEEN THE BASE YEAR AND THE PLANNING YEAR TO CALCULATE TOTAL EXPECTED CHANGE IN THE PATIENT DAY UTILIZATION RATE.

(v) ADD THE TOTAL EXPECTED CHANGE IN THE PATIENT DAY UTILIZATION RATE TO THE PATIENT DAY UTILIZATION RATE TO CALCULATE THE PATIENT DAY UTILIZATION RATE IN THE PLANNING YEAR.

(vi) DETERMINE THE “HIGH” AND “LOW” PATIENT DAY UTILIZATION RATE THRESHOLDS BY MULTIPLYING THE PATIENT DAY UTILIZATION RATE IN THE PLANNING YEAR BY 1.2 AND 0.8.

(b) FOR EACH PLANNING AREA, PERFORM THE FOLLOWING CALCULATIONS:

(i) DETERMINE THE PATIENT DAYS AND POPULATION FOR THE BASE YEAR.

(ii) DETERMINE THE PATIENT DAY UTILIZATION RATE PER 1000 PEOPLE FOR THE BASE YEAR DIVIDING THE PATIENT DAYS BY THE POPULATION AND MULTIPLYING BY 1000.

(iii) FOR EACH AGE COHORT, COMPARE THE PATIENT DAY UTILIZATION RATE TO THE PATIENT DAY UTILIZATION RATE THRESHOLDS OF THE HSA IN WHICH THE PLANNING AREA IS LOCATED.

(A) IF THE PLANNING AREA UTILIZATION RATE IS GREATER THAN THE HSA HIGH THRESHOLD, REPLACE THE PLANNING AREA UTILIZATION RATE WITH THE HSA HIGH THRESHOLD VALUE.

(B) IF THE PLANNING AREA UTILIZATION RATE IS LESS THAN THE HSA HIGH THRESHOLD, REPLACE THE PLANNING AREA UTILIZATION RATE WITH THE HSA LOW THRESHOLD VALUE.

(C) IF THE PLANNING AREA UTILIZATION RATE FALLS BETWEEN THE HSA LOW AND HIGH THRESHOLDS, IT IS UNCHANGED.

(iv) FOR EACH AGE COHORT, MULTIPLY THE PREDICTED POPULATION IN THE PLANNING YEAR BY THE PLANNING AREA UTILIZATION RATE DETERMINED IN SUBSECTION (2)(b)(iii) TO CALCULATE THE PREDICTED NUMBER OF PATIENT DAYS IN THE PLANNING YEAR.

(v) SUM THE PREDICTED NUMBER OF PATIENT DAYS IN THE PLANNING YEAR FOR EACH AGE COHORT TO CALCULATE THE TOTAL PREDICTED PATIENT DAYS.

(vi) DIVIDE THE TOTAL PREDICTED PATIENT DAYS BY 365 (OR 366 FOR LEAP YEARS) TO OBTAIN THE PREDICTED AVERAGE DAILY CENSUS (ADC).

(vii) DIVIDE THE ADC BY 0.90 TO OBTAIN THE NUMBER OF BEDS NEEDED FOR THE PLANNING AREA IN THE PLANNING YEAR.

Section 4. Bed need

Sec. 4. (1) The bed need numbers shall apply to project applications subject to review under these standards, except where a specific CON standard states otherwise.

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

(3) The base year and the planning year that shall be utilized in applying the methodology pursuant to subsection (2) shall be set according to the most recent data available to the Department.

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

(5) New bed need numbers established by subsections (2) and (3) shall supersede previous bed need numbers and shall be posted on the state of Michigan CON web site as part of the Nursing Home/HLTCU Bed Inventory.

(6) Modifications made by the Commission pursuant to this section shall not require standard advisory committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to become effective.

Section 5. Modification of the age specific use rates by changing the base year

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

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

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

Section 6. Requirements for approval to increase beds in a planning area

Sec. 6. An applicant proposing to increase the number of nursing home beds in a planning area must meet the following as applicable:

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

(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) Delinquent debt obligation to the State of Michigan including, but not limited to, Quality Assurance Assessment Program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or Civil Monetary Penalties (CMP).

(b) The applicant certifies that the requirements found in the Minimum Design Standards for Health Care Facilities of Michigan, referenced in Section 20145 (6) of the Public Health Code, Act 368 of 1978, as amended and are published by the Department, will be met when the architectural blueprints are submitted for review and approval by the Department.

(c) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

(d) The proposed increase, if approved, will not result in the total number of existing nursing home beds in that planning area exceeding the needed nursing home bed supply, unless one of the following is 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, the

difference is equal to or more than 1 and equal to or less than 20. This subsection is not applicable to projects seeking approval for beds from the statewide pool of beds.

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

(A) The applicant facility has experienced an average occupancy rate of 92% for the most recent 12 consecutive months and 90% or above for the prior 12 months as verifiable by the Department as of the date an application is submitted to the Department.

(B) The applicant facility has not decreased the number of licensed beds within the 24 months preceding the application date.

(C) The applicant facility shall propose no more than two beds per resident room and shall eliminate all three and/or four bed wards within the existing facility, if applicable, as part of the proposed project.

(D) The applicant facility shall certify the new beds for both Medicare and Medicaid.

(E) The applicant facility shall not relocate any beds from the facility or replace a portion of beds to a new site pursuant to Section 7(3)(d), following CON approval and for at least 24 months from the date of the licensure of the new beds at the facility.

~~(e) The applicant shall demonstrate that the planning area for the proposed project has an occupancy rate of 85% or more as published by the Department in the most recent CON Annual Survey reports.~~

(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) Delinquent debt obligation to the State of Michigan including, but not limited to, Quality Assurance Assessment Program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or Civil Monetary Penalties (CMP).

(b) The proposed project results in no more than 100 beds per new design model and meets the following design standards:

(i) For inpatient facilities that are not limited to group resident housing of 10 beds or less, the construction standards shall be those applicable to nursing homes in the document entitled Minimum Design Standards for Health Care Facilities in Michigan and incorporated by reference in Section 20145(6) of the Public Health Code, being Section 333.20145(6) of the Michigan Compiled Laws or any future versions.

(ii) For small resident housing units of 10 beds or less that are supported by a central support inpatient facility, the construction standards shall be those applicable to hospice residences providing an inpatient level of care, except that:

(A) at least 100% of all resident sleeping rooms shall meet barrier free requirements;

(B) electronic nurse call systems shall be required in all facilities;

(C) handrails shall be required on both sides of patient corridors; and

(D) ceiling heights shall be a minimum of 7 feet 10 inches.

(iii) The proposed project shall comply with applicable life safety code requirements and shall be fully sprinkled and air conditioned.

(iv) The Department may waive construction requirements for new design model projects if authorized by law.

(c) The proposed project shall include at least 80% single occupancy resident rooms with an adjoining toilet room containing a sink, water closet, and bathing facility and serving no more than two residents in both the central support inpatient facility and any supported small resident housing units.

(d) The proposed increase, if approved, will not result in the total number of existing nursing home beds in that planning area exceeding the needed nursing home bed supply, unless the following is met:

(i) An approved project involves replacement of a portion of the beds of an existing facility at a geographic location within the replacement zone that is not physically connected to the current licensed site. If a portion of the beds are replaced at a location that is not the current licensed site, a separate license shall be issued to the facility at the new location.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

~~(f) The applicant shall demonstrate that the planning area for the proposed project has an occupancy rate of 85% or more as published by the Department in the most recent CON Annual Survey reports.~~

Section 7. Requirements for approval to replace beds

Sec. 7. An applicant proposing to replace beds must meet the following as applicable.

(1) An applicant proposing to replace beds within the replacement zone shall not be required to be in compliance with the needed nursing home bed supply if all of the following requirements are met:

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

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing 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) Delinquent debt obligation to the State of Michigan including, but not limited to, Quality Assurance Assessment Program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or Civil Monetary Penalties (CMP).

(b) The proposed project is either to replace the licensed nursing home/HLTCU to a new proposed licensed site or replace a portion of the licensed beds at the existing licensed site.

(c) The proposed licensed site is within the replacement zone.

(d) The applicant certifies that the requirements found in the Minimum Design Standards for Health Care Facilities of Michigan, referenced in Section 20145 (6) of the Public Health Code, Act 368 of 1978, as amended and are published by the Department, will be met when the architectural blueprints are submitted for review and approval by the Department.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

(f) 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. THE REPLACEMENT FACILITY SHALL CERTIFY A SUFFICIENT NUMBER OF

MEDICAID BEDS TO SATISFY THE NEEDS OF THOSE CURRENT MEDICAID PATIENTS WHO DESIRE TO TRANSFER TO THE REPLACEMENT FACILITY/BEDS.

(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) Delinquent debt obligation to the State of Michigan including, but not limited to, Quality Assurance Assessment Program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or Civil Monetary Penalties (CMP).

(b) The total number of existing nursing home beds in that planning area is equal to or less than the needed nursing home bed supply.

(c) The number of beds to be replaced is equal to or less than the number of currently licensed beds at the nursing home/HLTCU at which the beds proposed for replacement are currently located.

(d) The applicant certifies that the requirements found in the Minimum Design Standards for Health Care Facilities of Michigan, referenced in Section 20145 (6) of the Public Health Code, Act 368 of 1978, as amended and are published by the Department, will be met when the architectural blueprints are submitted for review and approval by the Department.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

(f) 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. THE REPLACEMENT FACILITY SHALL CERTIFY A SUFFICIENT NUMBER OF MEDICAID BEDS TO SATISFY THE NEEDS OF THOSE CURRENT MEDICAID PATIENTS WHO DESIRE TO TRANSFER TO THE REPLACEMENT FACILITY/BEDS.

(3) An applicant proposing to replace beds with a new design model shall not be required to be in compliance with the needed nursing home bed supply if all of the following requirements are met:

(a) The proposed project results in no more than 100 beds per new design model and meets the following design standards:

(i) For inpatient facilities that are not limited to group resident housing of 10 beds or less, the construction standards shall be those applicable to nursing homes in the document entitled Minimum Design Standards for Health Care Facilities in Michigan and incorporated by reference in Section 20145(6) of the Public Health Code, being Section 333.20145(6) of the Michigan Compiled Laws or any future versions.

(ii) For small resident housing units of 10 beds or less that are supported by a central support inpatient facility, the construction standards shall be those applicable to hospice residences providing an inpatient level of care, except that:

(a) at least 100% of all resident sleeping rooms shall meet barrier free requirements;

(b) electronic nurse call systems shall be required in all facilities;

(c) handrails shall be required on both sides of patient corridors; and

(d) ceiling heights shall be a minimum of 7 feet 10 inches.

(iii) The proposed project shall comply with applicable life safety code requirements and shall be fully sprinkled and air conditioned.

(iv) The Department may waive construction requirements for new design model projects if authorized by law.

(b) The proposed project shall include at least 80% single occupancy resident rooms with an adjoining toilet room containing a sink, water closet, and bathing facility and serving no more than two residents in both the central support inpatient facility and any supported small resident housing units. If the proposed project is for replacement/renovation of an existing facility and utilizes only a portion of its currently licensed beds, the remaining rooms at the existing facility shall not exceed double occupancy.

(c) The proposed project shall be within the replacement zone unless the applicant demonstrates all of the following:

(i) the proposed licensed site for the replacement beds is in the same planning area,

(ii) the applicant shall provide a signed affidavit or resolution from its governing body or authorized agent stating that the proposed licensed site will continue to provide service to the same market, and

(iii) the current patients of the facility/beds being replaced shall be admitted to the replacement beds when the replacement beds are licensed, to the extent that those patients desire to transfer to the replacement facility/beds.

(d) An approved project may involve replacement of a portion of the beds of an existing facility at a geographic location within the replacement zone that is not physically connected to the current licensed site. If a portion of the beds are replaced at a location that is not the current licensed site, a separate license shall be issued to the facility at the new location. If beds have been added pursuant to Section 6(1)(d)(ii), then the applicant facility shall not relocate any beds from the facility or replace a portion of beds to a new site following CON approval and for at least 24 months from the date of the licensure of the new beds at the facility.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

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

Sec. 8. (1) An applicant proposing to relocate existing nursing home/HLTCU beds shall not be required to be in compliance with the needed nursing home bed supply if all of the following requirements are met:

(a) There shall not be any ownership relationship requirements between the nursing home/HLTCU from which the beds are being relocated and the nursing home/HLTCU receiving the beds.

(b) The relocated beds shall be placed in the same planning area.

(c) The relocated beds shall be licensed to the receiving nursing home/HLTCU and will be counted in the inventory for the applicable planning area.

(d) At the time of transfer to the receiving facility, patients in beds to be relocated must be given the choice of remaining in another bed in the nursing home/HLTCU from which the beds are being transferred or to the receiving nursing home/HLTCU. Patients shall not be involuntary discharged to create a vacant bed.

(e) Relocation of beds shall not increase the rooms with three (3) or more bed wards in the receiving facility.

(f) If beds have been added pursuant to Section 6(1)(d)(ii), then the applicant facility shall not relocate any beds from the facility or replace a portion of beds to a new site following ~~con~~ CON approval and for at least 24 months from the date of the licensure of the new beds at the facility.

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

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

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing 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) Delinquent debt obligation to the State of Michigan including, but not limited to, Quality Assurance Assessment Program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or Civil Monetary Penalties (CMP).

(b) The approval of the proposed new nursing home/HLTCU beds shall not result in an increase in the number of nursing home beds in the planning area.

(c) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

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

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

(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 for the planning area in which the nursing home or HLTCU is located if all of the following requirements are met:

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

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing 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) Delinquent debt obligation to the state of Michigan including, but not limited to, quality assurance assessment program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or civil monetary penalties (CMP).

(b) The acquisition will not result in a change in bed capacity.

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

(d) The project is limited solely to the acquisition of a nursing home/HLTCU with a valid license.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with the Department, and

(f) The applicant shall participate in a quality improvement program, approved by the Department, for five years and provide an annual report to the Michigan State Long-Term-Care Ombudsman, Bureau of Health Care Services within LARA, and shall post the annual report in the facility if the facility being acquired has met any of conditions in subsections (a)(i), (ii), (iii), (iv), (v), or (vi).

(g) If the applicant is a new entity with no prior NH-HLTCU history, the applicant shall submit proof that:

(i) The nursing home/HLTCU to be acquired is no longer listed as a special focus nursing home by the Center for Medicare and Medicaid Services, or the applicant shall participate in a quality improvement program, approved by the Department, for five years and provide an annual report to the Michigan State Long-Term-Care Ombudsman, Bureau of Health Care Services within LARA, and shall post the annual report in the facility; and

(ii) All delinquent debt obligations to the State of Michigan including, but not limited to, QAAP, PASARR or CMPs have been paid.

(2) An applicant proposing to acquire an existing nursing home/HLTCU approved pursuant to the new design model shall demonstrate the following:

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

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing 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) Delinquent debt obligation to the State of Michigan including, but not limited to, Quality Assurance Assessment Program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or Civil Monetary Penalties (CMP).

(b) An applicant will continue to operate the existing nursing home/HLTCU pursuant to the new design model requirements.

(c) The applicant shall participate in a quality improvement program, approved by the Department, for five years and provide an annual report to the Michigan State Long-Term-Care Ombudsman, Bureau of Health of Health Care Services within LARA, and shall post the annual report in the facility 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 Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

(e) If the applicant is a new entity with no prior NH-HLTCU history, the applicant shall submit proof that:

(i) The nursing home/HLTCU to be acquired is no longer listed as a special focus nursing home by the Center for Medicare and Medicaid Services, or the applicant shall participate in a quality improvement program, approved by the Department, for five years and provide an annual report to the Michigan State Long-Term-Care Ombudsman, Bureau of Health Care Services within LARA, and shall post the annual report in the facility; and

(ii) All delinquent debt obligations to the State of Michigan including, but not limited to, QAAP, PASARR OR CMPs have been paid.

(3) An applicant proposing to renew the lease for an existing nursing home/HLTCU shall not be required to be in compliance with the needed nursing home bed supply for the planning area in which the nursing home/HLTCU is located, if all of the following requirements are met:

(a) The lease renewal will not result in a change in bed capacity.

(b) The licensed site does not change as a result of the lease renewal.

(c) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

Section 10. Review standards for comparative review

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

(2) The degree to which each application in a comparative group meets the criterion set forth in Section 22230 of the Code, being Section 333.22230 of the Michigan Compiled Laws, shall be determined based on the sum of points awarded under subsections (a) and (b).

(a) A qualifying project will be awarded points as follows:

(i) For an existing nursing home/HLTCU, the current percentage of patient days of care reimbursed by Medicaid for the most recent 12 months of operation.

(ii) For a new nursing home/HLTCU, the proposed percentage of patient days of care to be reimbursed by Medicaid in the second 12 months of operation following project completion.

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

(b) A qualifying project will be awarded 10 points if all beds in the proposed project will be dually certified for both Medicare and Medicaid services by the second 12 months of operation.

(3) A qualifying project will have 15 points deducted if the applicant has any of the following at the time the application is submitted:

(a) has been a special focus nursing home/HLTCU within the last three (3) years;

(b) has had more than eight (8) substandard quality of care citations; immediate harm citations, and/or immediate jeopardy citations in the three (3) most recent standard survey cycles (includes intervening abbreviated surveys, standard surveys, and revisits);

(c) has had an involuntary termination or voluntary termination at the threat of a medical assistance provider enrollment and trading partner agreement within the last three (3) years;

(d) has had a state enforcement action resulting in a reduction in license capacity or a ban on admissions within the last three (3) years; or

(e) has any delinquent debt obligation to the state of Michigan including, but not limited to, quality assurance assessment program (QAAP), civil monetary penalties (CMP), Medicaid level of care determination (LOCD), or preadmission screening and annual resident review (PASARR).

(4) A qualifying project will be awarded three (3) points if the applicant provides documentation that it participates or if it proposes to participate in a culture change model, which contains person centered care, ongoing staff training, and measurements of outcomes. An additional five (5) points will be awarded if the culture change model, either currently used or proposed, is a model approved by the Department.

(5) A qualifying project will be awarded points based on the proposed percentage of the "Applicant's cash" to be applied toward funding the total proposed project cost as follows:

Percentage “Applicant’s Cash”	Points Awarded

Over 20%	5
10 – 20%	3
5 – 9%	2

(6) A qualifying project will be awarded four (4) points if the entire existing and proposed nursing home/HLTCU is fully equipped with air conditioning. Fully equipped with air conditioning means meeting the design temperatures in table 6b of the minimum design standards for health care facilities in Michigan and capable of maintaining a temperature of 71 – 81 degrees for the resident unit corridors.

(7) A qualifying project will be awarded six (6) or four (4) points based on only one of the following:
(a) Six (6) points if the proposed project has 100% rooms with dedicated toilet room containing a sink, water closet, and bathing facility or
(b) Four (4) points if the proposed project has 80% private rooms with dedicated toilet room containing a sink, water closet and bathing facility.

(8) A qualifying project will be awarded 10 points if it results in a nursing home/HLTCU with 150 or fewer beds in total.

(9) A qualifying project will be awarded five (5) points if the proposed beds will be housed in new construction.

(10) A qualifying project will be awarded 10 points if the entire existing nursing home/HLTCU and its proposed project will have no more than double occupancy rooms at completion of the project.

(11) A qualifying project will be awarded two (2) points if the existing or proposed nursing home/HLTCU is on or readily accessible to an existing or proposed public transportation route.

(12) A qualifying project will be awarded points for technological innovation as follows:

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

(13) A qualifying project will be awarded three (3) points if the proposed project includes bariatric rooms as follows: project using 0 – 49 beds will result in at least one (1) bariatric room or project using 50

or more beds will result in at least two (2) bariatric rooms. Bariatric room means the creation of patient room(s) included as part of the CON project, and identified on the architectural schematics, that are designed to accommodate the needs of bariatric patients weighing over 350 pounds. The bariatric patient rooms shall have a larger entrance width for the room and bathroom to accommodate over-sized equipment, and shall include a minimum of a bariatric bed, bariatric toilet, bariatric wheelchair, and a device to assist resident movement (such as a portable or build in lift). If an in-room shower is not included in the bariatric patient room, the main/central shower room that is located on the same floor as the bariatric patient room(s) shall include at least one (1) shower stall that has an opening width and depth that is larger than minimum MI code requirements.

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

(15) The Department shall approve those qualifying projects which, when taken together, do not exceed the need as defined in Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws, and which have the highest number of points when the results of subsections (2) through (12) are totaled. If two or more qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section 22225(1), in the order in which the applications were received by the Department, based on the date and time stamp on the application when the application is filed.

Section 11. Project delivery requirements and terms of approval

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

(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.

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

(a) Compliance with Section 22230 of the Code shall be based on the nursing home's/HLTCU's actual Medicaid participation within the time periods specified in these standards. Compliance with Section 10(2)(a) of these standards shall be determined by comparing the nursing home's/HLTCU's actual patient days reimbursed by Medicaid, as a percentage of the total patient days, with the applicable schedule set forth in Section 10(2)(a) for which the applicant had been awarded points in the comparative review process. If any of the following occurs, an applicant shall be required to be in compliance with the range in the schedule immediately below the range for which points had been awarded in Section 10(2)(a), instead of the range of points for which points had been awarded in the comparative review in order to be found in compliance with Section 22230 of the Code: (i) the average percentage of Medicaid recipients in all nursing homes/HLTCUs in the planning area decreased by at least 10 percent between the second 12 months of operation after project completion and the most recent 12-month period for which data are available, (ii) the actual rate of increase in the Medicaid program per diem reimbursement

to the applicant nursing home/HLTCU is less than the annual inflation index for nursing homes/HLTCUs as defined in any current approved Michigan State Plan submitted under Title XIX of the Social Security Act which contains an annual inflation index, or (iii) the actual percentage of the nursing home's/HLTCU's patient days reimbursed by Medicaid (calculated using total patient days for all existing and proposed nursing home beds at the facility) exceeds the statewide average plus 10 percent of the patient days reimbursed by Medicaid for the most recent year for which data are available from the Michigan Department of Health and Human Services [subsection (iii) is applicable only to Section 10(2)(a)]. 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.

(b) For projects involving the acquisition of a nursing home/HLTCU, the applicant shall agree to maintain the nursing home's/HLTCU's level of Medicaid participation (patient days and new admissions) for the time periods specified in these standards, within the ranges set forth in Section 10(2)(a) for which the seller or other previous owner/lessee had been awarded points in a comparative review.

(c) For projects involving replacement of an existing nursing home/HLTCU, the current patients of the facility/beds being replaced shall be admitted to the replacement beds when the replacement beds are licensed, to the extent that those patients desire to transfer to the replacement facility/beds.

(d) The applicant will assure compliance with Section 20201 of the Code, being Section 333.20201 of the Michigan Compiled Laws.

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

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

(i) not deny services to any individual based on payor source.

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

(iii) provide services to any individual based on clinical indications of need for the services.

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

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

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

(5) An applicant shall agree that, if approved, and material discrepancies are later determined within the reporting of the ownership and citation history of the applicant facility and all nursing homes under common ownership and control that would have resulted in a denial of the application, shall surrender the CON. This does not preclude an applicant from reapplying with corrected information at a later date.

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

Section 12. Department inventory of beds

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

Section 13. Wayne County planning areas

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

Planning Area 84/Northwest Wayne

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

Planning area 85/Southwest Wayne

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

Planning area 86/Detroit

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

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

Sec. 14. (1) These CON review standards supersede and replace the CON Standards for Nursing Home and Hospital Long-Term-Care Unit (HLTCU) Beds approved by the CON Commission on ~~December 11, 2014~~JUNE 18, 2020 and effective on ~~March 20, 2015~~SEPTEMBER 3, 2020.

(2) Projects reviewed under these standards involving a change in bed capacity shall be subject to comparative review except as follows:

(a) replacement of an existing nursing home/HLTCU being replaced in the replacement zone;

(b) replacement of an existing nursing home/HLTCU pursuant to Section 7(3) and within the same planning area as the existing licensed site;

(c) relocation of existing nursing home/HLTCU beds; or

(d) an increase in beds pursuant to Section 6(1)(d)(ii).

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

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 B

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CON REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS
--ADDENDUM FOR SPECIAL POPULATION GROUPS

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

Section 1. Applicability; definitions

Sec. 1. (1) This addendum supplements the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds and shall be used for determining the need for projects established to better meet the needs of special population groups within the long-term care and nursing home populations.

(2) Except as provided in sections 2, 3, 4, 5, 6, 7, and 8 of this addendum, these standards supplement, and do not supersede, the requirements and terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds.

(3) The definitions which apply to the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds shall apply to these standards.

(4) For purposes of this addendum, the following terms are defined:

(a) “Bariatric patient” means a patient weighting over 350 pounds.

(b) “Bariatric room” means the creation of patient room(s) included as part of the CON project, and identified on the architectural schematics, that are designed to accommodate the needs of bariatric patients weighing over 350 pounds. The bariatric patient rooms shall have a larger entrance width for the room and bathroom to accommodate over-sized equipment, and shall include a minimum of a bariatric bed, bariatric toilet, bariatric wheelchair, and a device to assist resident movement (such as a portable or build in lift). If an in-room shower is not included in the bariatric patient room, the main/central shower room that is located on the same floor as the bariatric patient room(s) shall include at least one (1) shower stall that has an opening width and depth that is larger than minimum MI Code requirements.

(c) "Behavioral patient" means an individual that exhibits a history of chronic behavior management problems such as aggressive behavior that puts self or others at risk for harm, or an altered state of consciousness, including paranoia, delusions, and acute confusion.

(d) "Infection control program," means a program that will reduce the risk of the introduction of communicable diseases into a ventilator-dependent unit, provide an active and ongoing surveillance program to detect the presence of communicable diseases in a ventilator-dependent unit, and respond to the presence of communicable diseases within a ventilator-dependent unit so as to minimize the spread of a communicable disease.

(e) "Licensed hospital" means either a hospital licensed under Part 215 of the Code; or a psychiatric hospital or unit licensed pursuant to Act 258 of the Public Acts of 1974, as amended, being sections 330.1001 to 330.2106 of the Michigan Compiled Laws.

(f) "Private residence", means a setting other than a licensed hospital; or a nursing home including a nursing home or part of a nursing home approved pursuant to Section 6.

(g) "Traumatic brain injury (TBI)/spinal cord injury (SCI) patient" means an individual with TBI or SCI that is acquired or due to a traumatic insult to the brain and its related parts that is not of a degenerative or congenital nature. These impairments may be either temporary or permanent and cause partial or total functional disability or psychosocial adjustment.

(h) "Ventilator-dependent patient," means an individual who requires mechanical ventilatory 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 1,039 beds and distributed as follows and shall be reduced/redistributed in accordance with subsection (c):

(i) TBI/SCI beds will be allocated 400 beds.

(ii) Behavioral beds will be allocated 400 beds.

(iii) Bariatric beds will be allocated 60 beds.

(iv) Ventilator-dependent beds will be allocated 179 beds.

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

(i) Alzheimer’s disease has 384 beds.

(ii) Health care needs for skilled nursing care has 173 beds.

(iii) Religious has 292 beds.

(iv) Hospice beds has 70 beds.

(c) The Commission may adjust/redistribute the number of beds available in the statewide pool for the needs of special population groups in subsection (1)(a) concurrent with the biennial recalculation of the statewide nursing home and hospital long-term care unit bed need. Modifying the number of beds available in the statewide pool for the needs of special population groups in subsection (1)(a) pursuant to this section shall not require a public hearing or submittal of the standard to the Legislature and the Governor in order to become effective.

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

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

Section 4. Requirements for approval for beds from the statewide pool for special population groups allocated to TBI/SCI patients

Sec. 4. The CON Commission determines there is a need for beds for applications designed to determine the efficiency and effectiveness of specialized programs for the care and treatment of TBI/SCI patients as compared to serving these needs in general nursing home unit(s).

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

(a) The beds will be operated as part of a specialized program exclusively for TBI/SCI patients. At the time an application is submitted, the applicant shall demonstrate that it operates:

(i) A continuum of outpatient treatment, rehabilitative care, and support services for TBI/SCI patients; and

(ii) A transitional living program or contracts with an organization that operates a transitional living program and rehabilitative care for TBI/SCI patients.

(b) The applicant shall submit evidence of accreditation of its existing outpatient and/or residential programs by the Commission on Accreditation of Rehabilitation Facilities (CARF) or another nationally-recognized accreditation organization for rehabilitative care and services.

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

(d) A floor plan for the proposed physical plant space to house the nursing home beds allocated under this subsection that provides for:

(i) Individual units consisting of 20 beds or less per unit, not to be more than 40 beds per facility.

(ii) Day/dining area within, or immediately adjacent to, the unit(s), which is solely for the use of TBI/SCI patients.

(iii) Direct access to a secure outdoor or indoor area at the facility appropriate for supervised activity.

(e) The applicant proposes programs to promote a culture within the facility that is appropriate for TBI/SCI patients of various ages.

(2) Beds approved under this subsection shall not be converted to or utilized as general nursing home use without a CON for nursing home and hospital long-term care unit beds under the CON review standards for nursing home and hospital long-term care unit beds and shall not be offered to individuals other than TBI/SCI patients.

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

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

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

(a) Individual units shall consist of 20 beds or less per unit.

(b) The facility shall not be awarded more than 40 beds.

(c) The proposed unit shall have direct access to a secure outdoor or indoor area for supervised activity.

(d) The unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the behavioral patients.

(e) The physical environment of the unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.

(f) Staff will be specially trained in treatment of behavioral patients.

(2) Beds approved under this subsection shall not be converted to or utilized as general nursing home use without a CON for nursing home and hospital long-term care unit beds under the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds.

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

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

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

(1) An applicant proposing to begin operation of a new nursing home/HLTCU or add beds to an existing nursing home/HLTCU under this section shall demonstrate, with credible documentation to the satisfaction of the Department, each of the following:

(a) The facility shall not be awarded more than 10 beds.

(b) The facility may place beds throughout the facility for a flexible and seamless inclusive resident design.

(c) The proposed beds shall have adequate access to an outdoor or indoor area for activities with appropriate equipment.

(d) The physical environment of any unit containing bariatric beds shall be designed to facilitate visitors.

(e) The unit/beds shall have available specialty equipment to assist staff in providing care.

(f) The beds shall be located on a ground floor and emergency egress will not require stairways or elevators to exit.

(g) The beds shall be established in either single or double occupancy rooms, there shall be no rooms with more than two beds.

(2) Beds approved under this subsection shall not be converted to or utilized for general nursing home use without a CON for nursing home and hospital long-term care unit beds.

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

Section 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.

(3) Beds approved under this subsection shall not be converted to or utilized for general nursing home use without a CON for nursing home and hospital long-term care unit beds.

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

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

(a) The applicant is a part of, closely affiliated with, controlled, sanctioned or supported by a recognized religious organization, denomination or federation as evidenced by documentation of its federal tax exempt status as a religious corporation, fund, or foundation under section 501(c)(3) of the United States Internal Revenue Code.

(b) The applicant's patient population includes a majority of members of the religious organization or denomination represented by the sponsoring organization.

(c) The applicant's existing services and/or operations are tailored to meet certain special needs of a specific religion, denomination or order, including unique dietary requirements, or other unique religious needs regarding ceremony, ritual, and organization which cannot be satisfactorily met in a secular setting.

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

(2) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to TBI/SCI shall meet the following:

(a) The beds will be operated as part of a specialized program exclusively for TBI/SCI patients. At the time an application is submitted, the applicant shall demonstrate that it operates:

(i) a continuum of outpatient treatment, rehabilitative care, and support services for TBI/SCI patients; and

(ii) a transitional living program or contracts with an organization that operates a transitional living program and rehabilitative care for TBI/SCI patients.

(b) The applicant shall submit evidence of accreditation of its existing outpatient and/or residential programs by the Commission on Accreditation of Rehabilitation Facilities (CARF) or another 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 bariatric patients shall meet the following:

(a) The facility shall not be awarded more than 10 beds.

(b) The facility may place beds throughout the facility for a flexible and seamless inclusive resident design.

(c) The proposed beds shall have adequate access to an outdoor or indoor area for activities with appropriate equipment.

(d) The physical environment of any unit containing bariatric beds shall be designed to facilitate visitors.

(e) The beds shall have available specialty equipment to assist staff in providing care.

(f) The beds shall be located on a ground floor and emergency egress will not require stairways or elevators to exit.

(g) Beds approved under this subsection shall not be converted to or utilized as general nursing home use without a CON for nursing home and hospital long-term care unit beds under the CON review standards.

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

(7) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to ventilator-dependent patients shall meet the following:

(a) An applicant proposes a program for caring for ventilator-dependent patients in licensed nursing home beds.

(b) An application proposes no more than 40 beds that will be licensed as nursing home beds.

(c) The proposed unit will serve only ventilator-dependent patients.

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

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

Sec. 9. (1) An applicant shall agree that if approved, the services shall be delivered in compliance with the terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds.

(2) An applicant for beds from the statewide pool for special population groups allocated to religious shall agree that, if approved, the services provided by the specialized long-term care beds shall be delivered in compliance with the following term of CON approval:

(a) The applicant shall document, at the end of the third year following initiation of beds approved an annual average occupancy rate of 95 percent or more. If this occupancy rate has not been met, the applicant shall delicense a number of beds necessary to result in a 95 percent occupancy based upon its average daily census for the third full year of operation.

(3) An applicant for beds from the statewide pool for special population groups allocated to Alzheimer’s disease shall agree that if approved:

(a) The beds are part of a specialized program for Alzheimer's disease which will admit and treat only patients which require long-term nursing care and have been appropriately classified as a patient on the Global Deterioration Scale (GDS) for age-associated cognitive decline and Alzheimer's disease as a level 4 (when accompanied by continuous nursing needs), 5, or 6.

(b) The specialized program will participate in the state registry for Alzheimer's disease.

(c) The specialized program shall be attached or geographically adjacent to a licensed nursing home and be no larger than 20 beds in size.

(d) The proposed Alzheimer's unit shall have direct access to a secure outdoor or indoor area at the health facility, appropriate for unsupervised activity.

(e) The Alzheimer's unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the Alzheimer's unit patients.

(f) The physical environment of the Alzheimer's unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.

(g) Staff will be specially trained in Alzheimer's disease treatment.

(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.

(8) An applicant for beds from the statewide pool for special population groups allocated to bariatric patients shall agree that if approved:

(a) The facility shall not be awarded more than 10 beds.

(b) The facility may place beds throughout the facility for a flexible and seamless inclusive resident design.

(c) The proposed beds shall have adequate access to an outdoor or indoor area for activities with appropriate equipment.

(d) The physical environment of any unit containing bariatric beds shall be designed to facilitate visitors.

(e) The beds shall have available specialty equipment to assist staff in providing care.

(f) The beds shall be located on a ground floor and emergency egress will not require stairways or elevators to exit.

(g) The beds shall be established in either single or double occupancy rooms. There shall be no rooms with more than two beds.

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

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

Sec. 10. (1) Projects proposed under Section 4 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

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

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

(4) Projects proposed under Section 7 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

(5) These CON review standards supercede and replace the CON Review Standards for Nursing Home and Long-term Care Unit Beds--Addendum for Special Population Groups approved by the Commission on December 11, 2014 and effective on March 20, 2015.

Trinity Health
Livonia, MI

August 24, 2020

Mr. James Falahee, Chair, CON Commission
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

Dear Chairman Falahee,

I write to request that the Michigan CON Commission, at it's next scheduled meeting on September 17, 2020, consider an additional charge to the Hospital Beds Standard Advisory Committee (SAC), currently in formation, allowing for a review of the current definition of "Replacement Zone" in the Hospital Beds Standard.

The current definition of Replacement Zone in the Hospital Bed Standards limits the replacement of hospital beds to the same site, a contiguous site or 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. We believe this language needs to be reviewed to consider population shifts in counties where only one hospital is providing 24/7 Emergency Services in the county.

As population shifts have occurred across Michigan and specifically within county borders, the location of a general acute care hospital providing 24/7 emergency services may be geographically distant from the population center of the county in which the hospital is located. In order to ensure that 24/7 healthcare services offered by a general acute care hospital are located in proximity to the greatest number of county residents in these communities, we believe the current replacement zone mileage restriction should be reconsidered. We would welcome an opportunity to present our thoughts on how to address this issue within the charge of the current Hospital Bed SAC.

If the Commission agrees to this additional charge we would offer the following language for your consideration: "*Review the hospital replacement zone provisions to ensure adequate acute care access in counties where only one hospital providing 24/7 emergency services exists in the county.*"

Thank you in advance for your consideration of this request. If you have any questions regarding this request please do not hesitate to contact me directly or Sean Gehle at the Trinity Health – Michigan Advocacy office at 248-225-7240.

Sincerely,

Rob Casalou,

President & CEO Trinity Health Michigan and Southeast region

cc: Beth Nagel, Division Director, Policy and Planning Administration, MDHHS

STATE OF MICHIGAN

GRETCHEN WHITMER,
Governor

Michigan Certificate of Need Commission

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Lorissa MacAllister, PhD
Amy McKenzie, MD
Tom Mittelbrun III, Vice-Chairperson
Melisa Oca, MD

MEMORANDUM

Date: September 17, 2020

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 CON 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*." 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*." This report is intended to fulfill these requirements.

To start, we would like to remind the JLC that the CON Commission is composed of 11 volunteers and oversees 15 covered services. The CON Commissioners receive no compensation for their services, other than reimbursement for travel expenses. The CON 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 Michigan Department of Health and Human Services ("Department") supports the CON Commission and administers the CON program.

The CON Commission respectfully submits the following bi-annual report:

Based on our continuous review of the program, the CON Commission believes and recommends that the program should be fully supported as it is serving a valuable need. In our bi-partisan judgment, we strongly believe the current CON process meets the statutory requirements for the program.

Our review of the program is based on reports provided to the Commission by the Department which is done at the close of every fiscal year. The FY2019 CON Program Annual Activity Report can be found here https://www.michigan.gov/documents/mdhhs/FY_2019_CON_Annual_Report_Final_699883_7.pdf. The FY2020 CON Program Annual Activity Report should be available in January 2021 and will be available here: https://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5106-126234--,00.html.

In addition to 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.

We would like to provide the JLC a summary of our activities and accomplishments since the January 2019 report. In the last two years, the Commission has updated 8 of the 15 Review Standards for covered services, including:

- Hospital Beds
- Cardiac Catheterization Services
- Open Heart Surgery Services
- Megavoltage Radiation Therapy (MRT)
- Psychiatric Beds and Services
- Immune Effector Cell Therapy (IECT) Services
- Nursing Home and Hospital Long-Term-Care Unit (NH-HLTCU) Beds
- Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services

In some instances, technical changes were made to modernize standards and/or remove unnecessary regulation. In other instances, major changes were made to benefit the cost, quality and/or access of healthcare for Michigan citizens. Standards were developed for a new service to be covered under CON.

A summary of the changes that have been put into effect or are being proposed to the CON Review Standards during FY2019 and FY2020 is included in Attachment A in an overview chart and in greater detail in Attachment B.

All changes to CON standards, both technical and policy, have been made with the multiple opportunities for public input and with the recommendations of subject matter experts. The statutory process for modifying CON standards includes holding a public hearing before the CON Commission takes final action on any standard. The Commission actively seeks input from the public during the CON Commission meetings and always includes opportunities for public comment/hearings prior to any Commission action.

The CON Commission is currently in process seeking recommendations for modifications to four CON review standards. At the time of this report, there is a Standard Advisory Committee (SAC) reviewing Cardiac Catheterization Services, a SAC is reviewing Hospital Beds, a workgroup will be seated to review MRI Services, and a workgroup will be seated to review PET Scanner Services.

The following review standards will be reviewed in 2021: Bone Marrow Transplantation (BMT) Services, Heart/Lung and Liver Transplantation Services, Magnetic Resonance Imaging (MRI) Services, and Psychiatric Beds and Services.

Per our statutory obligation, the CON Commission submits that there are no statutory changes needed to improve the Certificate of Need program at this time.

The CON Commission appreciates the continuing support of the Governor and the Legislature for the CON program.

Respectfully yours,

James B. Falahee, Jr, JD, Chairperson

Tom Mittelbrun III, Vice-Chairperson

c: CON Commission
Robert Gordon, Director, MDHHS
Elizabeth Hertel, Chief Deputy Director for Administration, MDHHS
Sarah Esty, Senior Deputy Director of Policy and Planning, MDHHS
Emily Schwarzkopf, Director of Legislative, Appropriations, and Constituent Affairs, MDHHS
Becky Berels, Assistant Attorney General, Corporate Oversight Division
Beth Nagel, Planning Office Director, MDHHS
Tulika Bhattacharya, Manager, CON Evaluation Section, MDHHS
Brenda Rogers, Special Assistant to the CON Commission, MDHH

SUMMARY OF CON REVIEW STANDARDS REVISIONS FOR FISCAL YEARS 2019 AND 2020 - ATTACHMENT A

Fiscal Year	Standard	Commission Plan for Review	Review Process	Summary of Major Changes Made/Proposed
2019	Hospital Beds	Formed a Standard Advisory Committee (SAC)	• SAC held July - December 2017 • CON Commission took Proposed Action at March 27, 2018 meeting • Public Hearing Held April 26, 2018 • CON Commission took Final Action at June 14, 2018 meeting • Standards became effective November 28, 2018	• Added inpatient rehabilitation facility beds initiation & replacement requirements • Removed unnecessary regulatory requirements regarding relocating beds • Modernized comparative review requirements • Added renewal of lease requirements
2019	Cardiac Catheterization	Formed a SAC	• SAC held July - December 2017 • CON Commission took Proposed Action at March 27, 2018 meeting • Public Hearing Held April 26, 2018 • CON Commission took Proposed Action at June 14, 2018 meeting • Public Hearing Held July 19, 2018 • CON Commission took Final Action at September 20, 2018 meeting • Standards became effective December 26, 2018	• Modified and updated definitions • Pacemakers and implantable cardioconverter defibrillators can only be performed in licensed hospitals with diagnostic CC CON approval • Added requirements for replacement of a cardiac catheterization service simultaneously with an open heart surgery service • Updated project delivery requirements • Updated procedure equivalents
2019	Open Heart Surgery (OHS) Services	Language dependent upon Cardiac Catheterization SAC and language drafted by the Department	• CON Commission took Proposed Action at March 27, 2018 meeting • Public Hearing Held April 26, 2018 • CON Commission took Proposed Action at June 14, 2018 meeting • Public Hearing Held July 19, 2018 • CON Commission took Final Action at September 20, 2018 meeting • Standards became effective December 26, 2018	• Added requirements for replacement of an open heart surgery service
2019	Megavoltage Radiation Therapy (MRT) Services/Units	Formed a SAC	• SAC held June - December 2018 • CON Commission took Proposed Action at March 21, 2019 meeting • Public Hearing Held April 25, 2019 • CON Commission took Final Action at June 13, 2019 meeting • Standards became effective September 12, 2019	• Revised procedure weights and added additional factors and definitions • Reduced the maintenance volume

SUMMARY OF CON REVIEW STANDARDS REVISIONS FOR FISCAL YEARS 2019 AND 2020 - ATTACHMENT A

Fiscal Year	Standard	Commission Plan for Review	Review Process	Summary of Major Changes Made/Proposed
2019 & 2020	Psychiatric Beds and Services	Form a Workgroup	• Workgroup held August 2018 - March 2019 • CON Commission took Proposed Action at December 26, 2018 meeting • Public Hearing Held February 6, 2019 • CON Commission took Final Action at March 21, 2019 meeting • Standards became effective May 24, 2019 • CON Commission took Proposed Action at June 13, 2019 meeting • Public Hearing Held July 25, 2019 • CON Commission took Final Action at September 19, 2019 meeting • Standards became effective November 12, 2019	• Added relocation requirements for child/adolescent psychiatric services • Developed a new bed need methodology for child/adolescent and adult beds • Added minimum occupancy requirements • Updated comparative review requirements • Added high acuity psychiatric units • Increased the percentage for determining the number of special pool beds • Revised the standard for med-psych units
2020	Immune Effector Cell Therapy (IECT) Services	Formed a SAC	• SAC held February - April 2019 • CON Commission took Proposed Action at June 13, 2019 meeting • Public Hearing Held July 25, 2019 • CON Commission took Final Action at September 19, 2019 meeting • Legislature took negative action – standards did not go into effect	
2020	Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	Department to draft language based on public testimony	• CON Commission took Proposed Action at the June 13, 2019 meeting • Public Hearing held July 25, 2019 • CON Commission took Final Action at September 19, 2019 meeting • Standards became effective November 12, 2019	• Reduced the volume requirements
2020	Nursing Home and Hospital Long-Term-Care Unit Beds (NH-HLTCU)	Formed a Standard SAC	• SAC held December, 2019 – January, 2020 • CON Commission took Proposed Action at the January 30, 2020 meeting • Public Hearing held February 11, 2020 • CON Commission took Final Action at June 18, 2020 meeting • Standards became effective September 3, 2020	• Added language that requires a planning area to have an occupancy rate of 85% or more to be able to begin operation of a new NH-HLTCU or to increase the number of beds at an existing licensed NH-HLTCU.

SUMMARY OF CON REVIEW STANDARDS REVISIONS FOR FISCAL YEARS 2019 AND 2020 - ATTACHMENT A

Fiscal Year	Standard	Commission Plan for Review	Review Process	Summary of Major Changes Made/Proposed
2020/ 2021	Computed Tomography (CT) Scanner Services	Formed a Workgroup		• This Workgroup is charged to determine if 24-hour freestanding emergency departments should be exempt from meeting the maintenance volume for its first CT scanner; review the definition and requirements for dedicated pediatric CT scanners; and review the maintenance volume requirements.
2020/ 2021	Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services	Formed a Workgroup		• This Workgroup is charged to determine if high flow nasal cannula treatment and neonatal abstinence syndrome should be included as accepted services for special care nurseries; determine if telemedicine can be used as an acceptable replacement for on-site services; review the high occupancy provisions and occupancy requirements; review a possible minimum NICU size exception for rural or micropolitan counties; and review the definition of NICU services.
2020/ 2021	NH-HLTCU	Formed a Standard SAC		• This SAC is charged to review the bed need methodology; review whether adequate access exists for Medicaid patients; review specialty population beds; review language for minimum occupancy requirements; review changes for replacement.
2020/ 2021	Cardiac Catheterization Services	Formed a SAC		• This SAC is charged to review all minimum volume requirements; review increased exceptions for more rural programs; review allowing patent foramen ovale (PFO) closures in facilities without open heart surgery (OHS); review if diagnostic cardiac catheterization services, elective PCI procedures, and pacemakers and implantable cardioverter defibrillator (ICD) implants should be allowed to be performed in ambulatory surgical centers (ASCs); review the ability of elective PCI programs and hospitals that provide primary PCI without on-site OHS to perform left-sided cardiac ablation procedures.
2020/ 2021	Hospital Beds	Form a SAC		• The SAC is charged to review limited access areas; review observation status; and add definition for "verifiable data."

SUMMARY OF CON REVIEW STANDARDS REVISIONS FOR FISCAL YEARS 2019 AND 2020 - ATTACHMENT A

Fiscal Year	Standard	Commission Plan for Review	Review Process	Summary of Major Changes Made/Proposed
2020/ 2021	Positron Emission Tomography (PET) Scanner Services	Form a Workgroup		• The Workgroup is charged to review the oversight requirements to initiate mobile and fixed services; review minimum volume requirement to convert to a fixed service; and review if specific requirements should be added to the PET standards for fixed novel whole-body PET/CT and PET/MR scanners located immediately adjacent to a modern cyclotron-equipped radiopharmacy.
2020/ 2021	Magnetic Resonance Imaging (MRI) Services	Form a Workgroup		• The Workgroup is charged to Review minimum volume requirements for fixed and mobile MRI.

DETAILS OF CON REVIEW STANDARDS REVISIONS FOR FISCAL YEARS 2019 AND 2020 - ATTACHMENT B

During FY2019, the CON Commission revised the review standards for Hospital Beds, Cardiac Catheterization Services, Open Heart Surgery Services, Megavoltage Radiation Therapy (MRT), and Psychiatric Beds and Services.

The following list of changes shows new language inserted into the standards in all upper case.

Hospital Beds: The revisions to the CON Review Standards for Hospital Beds include the following and became effective on November 28, 2018.

- Updated the Department name throughout the document.
- Section 2(1) - Added and modified definitions as follows:
    - (v) "INPATIENT REHABILITATION FACILITY BED" OR "IRF BED" MEANS A LICENSED HOSPITAL BED WITHIN AN IRF HOSPITAL OR UNIT 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.
    - (mm) "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.
    - (oo) "REPLACE IRF BEDS" MEANS A CHANGE IN THE LOCATION OF ALL IRF BEDS FROM AN EXISTING SITE TO A NEW SITE WITHIN THE REPLACEMENT ZONE FOR IRF BEDS.
    - (pp) "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 (5 MILES FOR IRF BEDS) 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 (10 MILES FOR IRF BEDS) of the existing licensed site if the existing licensed site is located in a county with a population of less than 200,000.
- Section 6(4)(a) - Added language to allow for beds received under high occupancy to be replaced to a new IRF hospital site under Section 7(6).
    - The beds are being added at the existing licensed hospital site OR ARE BEING REPLACED TO A NEW IRF HOSPITAL SITE BEING CREATED UNDER SECTION 7(7) AS PART OF THE SAME CON APPLICATION.
- Section 6(4)(f) - Removed language that required applicants adding new hospital beds under high occupancy to pursue a good faith effort to relocate acute care beds from other licensed acute care hospitals within the HSA as it's not deemed necessary.
- Section 7 – Added language to replace IRF beds to a new site as follows:
    - (2) The applicant shall specify whether the proposed project is to replace the licensed hospital to a new site, TO REPLACE ALL LICENSED IRF BEDS TO A NEW SITE, 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(s) or street(s) as defined in MCL 257.20 and excludes a new site across a limited access highway as defined in MCL 257.26.
    - (6) IF THE APPLICATION INVOLVES THE DEVELOPMENT OF A NEW

DETAILS OF CON REVIEW STANDARDS REVISIONS FOR FISCAL YEARS 2019 AND 2020 - ATTACHMENT B

LICENSED IRF HOSPITAL SITE, AN APPLICANT PROPOSING TO REPLACE IRF BEDS WITHIN THE REPLACEMENT ZONE SHALL DEMONSTRATE THAT IT MEETS ALL OF THE REQUIREMENTS OF THIS SUBSECTION:

- (a) THE NEW LICENSE CREATED BY THE PROPOSED PROJECT SHALL ONLY BE UTILIZED FOR INPATIENT REHABILITATION BEDS.
- (b) THE APPLICANT HOSPITAL HAS DEMONSTRATED, AT THE TIME OF THE CON FILING, IT IS OPERATING UNDER HIGH OCCUPANCY AS GOVERNED BY SECTION 6(4) OF THESE STANDARDS.
- (c) THE APPLICANT HAS DEMONSTRATED, AT THE TIME OF CON FILING, THAT THE BEDS TO BE REPLACED ARE EITHER IRF BEDS THAT MEET THE TITLE XVIII REQUIREMENTS OF THE SOCIAL SECURITY ACT FOR EXEMPTION FROM PPS AS AN IRF HOSPITAL, OR HIGH OCCUPANCY BEDS BEING REQUESTED UNDER SECTION 6(4) AS PART OF THE SAME CON APPLICATION.
- (d) THE NEW IRF HOSPITAL WILL HAVE AT LEAST 40 IRF BEDS IF LOCATED IN A COUNTY WITH A POPULATION OF 200,000 OR MORE; OR AT LEAST 25 IRF BEDS IF LOCATED IN A COUNTY WITH A POPULATION OF LESS THAN 200,000.
- (e) AS PART OF THE PHASING OF THE REPLACEMENT OF IRF BEDS TO THE NEW SITE, THE APPLICANT MAY RETAIN, FOR 36-MONTHS FROM THE TIME OF ACTIVATION OF THE NEW SITE, UP TO EIGHT IRF BEDS AT THE EXISTING HOSPITAL SITE. ANY IRF BEDS AT THE EXISTING SITE THAT HAVE NOT BEEN TRANSITIONED TO THE NEW SITE WITHIN THE 36-MONTH TIME PERIOD SHALL NOT BE UTILIZED FOR INPATIENT REHABILITATION AND SHALL REVERT BACK TO ACUTE MEDICAL-SURGICAL HOSPITAL BEDS.
- (f) THE PROPOSED PROJECT TO BEGIN OPERATION OF A NEW SITE, UNDER THIS SUBSECTION, SHALL CONSTITUTE A CHANGE IN BED CAPACITY UNDER SECTION 1(2) OF THESE STANDARDS.
- (g) THE EXISTING HOSPITAL SITE SHALL DELICENSE THE SAME NUMBER OF IRF BEDS PROPOSED BY THE APPLICANT FOR LICENSURE IN THE NEW IRF HOSPITAL.
- (h) APPLICANTS PROPOSING A NEW IRF HOSPITAL UNDER THIS SUBSECTION SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW.
- (i) THE NEW IRF HOSPITAL SHALL BE ASSIGNED TO THE SAME HOSPITAL GROUP AS THE HOSPITAL WHERE THE IRF BEDS ORIGINATED.
- (j) IF THE IRF HOSPITAL APPROVED UNDER THIS SUBSECTION CEASES OPERATION AS AN IRF HOSPITAL, THE BEDS LICENSED AS PART OF THE NEW IRF HOSPITAL MUST BE DISPOSED OF BY ONE OF THE FOLLOWING MEANS:
- (i) RELOCATE THE REPLACED IRF BEDS BACK TO THE SITE OF ORIGIN;
- (ii) RELOCATE ALL IRF BEDS APPROVED UNDER HIGH OCCUPANCY TO THE SITE OF ORIGIN IN SUBSECTION (i) IF THEY ARE TO BE UTILIZED AS AN IRF BED; OR
- (iii) DELICENSE ANY IRF BEDS APPROVED UNDER HIGH OCCUPANCY IF THEY ARE NOT TO BE UTILIZED AS AN IRF BED.

- Section 12 – Updated comparative review criteria.
- Old Section 13 – Removed and combined with Section 12.
- New Section 13 – Added language for the renewal of a lease similar to other CON Review Standards.

DETAILS OF CON REVIEW STANDARDS REVISIONS FOR FISCAL YEARS 2019 AND 2020 - ATTACHMENT B

- New Section 14(4) – Added new language for the applicant to certify that the requirements for hospitals found in the Minimum Design Standards for Health Care Facilities of Michigan will be met when the architectural blueprints are submitted for review and approval by Licensing and Regulatory Affairs (LARA). This is similar to other CON Review Standards.
- Removal of Appendix D Limited Access Areas as it's located on the State of Michigan CON web site. All references have been updated to reflect the State of Michigan CON web site. Appendix E is now Appendix D ICD-9-CM TO ICD-10-CM Code Translation.
- Other technical edits.

Cardiac Catheterization Services: The revisions to the CON Review Standards for Cardiac Catheterization Services include the following and became effective on December 26, 2018:

- Updated the Department name throughout the document.
- Added "hospital" after "applicant" throughout the document, as applicable, for clarity.
- Added "/congenital" after "pediatric" throughout the document, as applicable, for clarity.
- Section 2(1) - Added and modified definitions as follows:
    - (a) "ADULT CARDIAC CATHETERIZATION SERVICE" MEANS PROVIDING CARDIAC CATHETERIZATION SERVICES ON AN ORGANIZED, REGULAR BASIS TO PATIENTS AGE 18 AND ABOVE, AND FOR ELECTROPHYSIOLOGY PROCEDURES TO PATIENTS AGE 15 AND OLDER.
    - (b) "Cardiac catheterization laboratory" or "laboratory" means an individual radiological room equipped with a variety of x-ray machines and devices such as electronic image intensifiers, high speed film changers and digital subtraction units to assist in performing diagnostic or therapeutic cardiac catheterizations or electrophysiology studies.
    - (c) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, performed on a patient during a single session in a laboratory. Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X rays and an electronic image intensifier are used as aides in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart. This term does not include "float catheters" that are performed at the bedside or in settings outside the laboratory or the implantation of cardiac permanent pacemakers and implantable cardioverter defibrillators (ICD) devices that are performed in an interventional radiology laboratory or operating room IN A LICENSED HOSPITAL AND HAS DIAGNOSTIC CARDIAC CATHETERIZATION CON APPROVAL.
    - (d) "Cardiac catheterization service" means the provision of one or more of the following types of procedures: adult diagnostic cardiac catheterizations; adult therapeutic cardiac catheterizations; and pediatric/CONGENITAL cardiac catheterizations.
    - (e) "CARDIAC CATHETERIZATION SESSION" MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC OR THERAPEUTIC CARDIAC OR PERIPHERAL PROCEDURES IN A CARDIAC CATHETERIZATION LABORATORY. THE TERM SESSION APPLIES TO BOTH ADULT AND PEDIATRIC/CONGENITAL CATHETERIZATIONS.
    - (h) "COMPLEX THERAPEUTIC SESSION" MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT UNDERGOES ONE OR MORE OF THE

DETAILS OF CON REVIEW STANDARDS REVISIONS FOR FISCAL YEARS 2019 AND 2020 - ATTACHMENT B

FOLLOWING PROCEDURES:

- (i) PCI FOR CHRONIC TOTAL OCCLUSION
- (ii) TAVR, MITRAL/PULMONARY/TRICUSPID VALVE REPAIR OR REPLACEMENT, PARAVALVULAR LEAK CLOSURE
- (iii) ABLATION FOR ATRIAL FIBRILLATION (AF) OR VENTRICULAR TACHYCARDIA (VT), PACEMAKER OR ICD LEAD EXTRACTION
- (j) “DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURE” INCLUDES RIGHT HEART CATHETERIZATION, LEFT HEART CATHETERIZATION, CORONARY ANGIOGRAPHY, CORONARY ARTERY BYPASS GRAFT ANGIOGRAPHY, INTRACORONARY ADMINISTRATION OF DRUGS, FRACTIONAL FLOW RESERVE (FFR), INTRA-CORONARY IMAGING SUCH AS INTRAVASCULAR ULTRASOUND (IVUS), OPTICAL COHERENCE TOMOGRAPHY (OCT), OR NEAR-INFRARED SPECTROSCOPY (NIRS) WHEN PERFORMED WITHOUT A THERAPEUTIC PROCEDURE, CARDIAC BIOPSY, INTRA-CARDIAC ECHOCARDIOGRAPHY, AND ELECTROPHYSIOLOGY STUDY.
- (k) "Diagnostic cardiac catheterization service" means providing diagnostic cardiac catheterization procedures on an organized, regular basis in a laboratory to diagnose anatomical and/or physiological problems in the heart. Procedures include the intra coronary administration of drugs; left heart catheterization; right heart catheterization; coronary angiography; diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic). A hospital that provides diagnostic cardiac catheterization services may also perform implantations of cardiac permanent pacemakers and ICD devices IMPLANTATION (THERAPEUTIC PROCEDURES).
- (l) “DIAGNOSTIC CARDIAC CATHETERIZATION SESSION” MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES.
- (m) “DIAGNOSTIC PERIPHERAL PROCEDURE” INCLUDES ANGIOGRAPHY OR HEMODYNAMIC MEASUREMENTS IN THE ARTERIAL OR VENOUS CIRCULATION (EXCLUDING THE HEART).
- (n) “DIAGNOSTIC PERIPHERAL SESSION” MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC PERIPHERAL ROCEDURES IN A CARDIAC CATHETERIZATION LABORATORY.
- (p) “Elective PCI services without on-site open heart surgery (OHS)” means performing PCI, percutaneous transluminal coronary angioplasty (PTCA), and coronary stent implantation on an organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary PCI service but not having OHS on-site and adhering to patient selection as outlined in the SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site Surgical Backup and published in Circulation 2014, 129:2610-2626 and its update or further guideline changes. A HOSPITAL THAT PROVIDES ELECTIVE PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM RIGHT-SIDED CARDIAC ABLATION PROCEDURES INCLUDING RIGHT ATRIAL FLUTTER, AV REENTRY, AV NODE REENTRY, RIGHT ATRIAL TACHYCARDIA, AND AV NODE ABLATION.
- (t) "Pediatric/CONGENITAL cardiac catheterization service" means providing cardiac AND ELECTROPHYSIOLOGY catheterization services on an organized, regular basis to infants and children ages 18 and below, except for electrophysiology studies that are offered and provided to infants and children ages 14 and below, and PATIENTS BORN with congenital heart disease.

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- (u) “PERCUTANEOUS CORONARY INTERVENTION” (PCI) MEANS A THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURE TO RESOLVE ANATOMIC AND/OR PHYSIOLOGIC PROBLEMS IN THE CORONARY ARTERIES OF THE HEART. A PCI SESSION MAY INCLUDE SEVERAL PROCEDURES INCLUDING BALLOON ANGIOPLASTY, ATHERECTOMY, LASER, STENT IMPLANTATION AND THROMBECTOMY. THE TERM DOES NOT INCLUDE THE INTRACORONARY ADMINISTRATION OF DRUGS, FFR OR IVUS WHERE THESE ARE THE ONLY PROCEDURES PERFORMED.
- (v) “PERIPHERAL CATHETERIZATION SESSION” MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC OR THERAPEUTIC PROCEDURES IN THE ARTERIAL OR VENOUS CIRCULATION (EXCLUDING THE HEART) WHEN PERFORMED IN A CARDIAC CATHETERIZATION LABORATORY.
- (w) “Primary percutaneous coronary intervention (PCI)” means a PCI performed on an EMERGENT BASIS ON A acute myocardial infarction (AMI) patient with confirmed ST-SEGMENT elevation, or new left bundle branch block on an emergent basis, ECG EVIDENCE OF TRUE POSTERIOR MI, OR CARDIOGENIC SHOCK.
- (x) “Primary PCI service without on-site OHS” means performing primary PCI on an emergent basis in a hospital having a diagnostic cardiac catheterization service. A HOSPITAL THAT PROVIDES PRIMARY PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM RIGHT-SIDED CARDIAC ABLATION PROCEDURES INCLUDING RIGHT ATRIAL FLUTTER, AV REENTRY, AV NODE REENTRY, RIGHT ATRIAL TACHYCARDIA, AND AV NODE ABLATION.
- (y) "Procedure equivalent" means a unit of measure that reflects the relative average length of time one patient spends in one session in a CARDIAC CATHETERIZATION laboratory based on the type of procedures being performed. IF A DIAGNOSTIC AND THERAPEUTIC PROCEDURE IS PERFORMED IN THE SAME SESSION, THE HIGHER PROCEDURE EQUIVALENT WEIGHTING WILL BE USED TO EVALUATE UTILIZATION.
- (z) “STRUCTURAL HEART PROCEDURE” MEANS A THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURE TO RESOLVE ANATOMIC AND/OR PHYSIOLOGIC PROBLEMS OF THE HEART VALVES OR CHAMBERS. PROCEDURES INCLUDE: BALLOON VALVULOPLASTY, BALLOON ATRIAL SEPTOSTOMY, TRANSCATHETER VALVE REPAIR, TRANSCATHETER VALVE IMPLANTATION, PARAVALULAR LEAK CLOSURE, LEFT ATRIAL APPENDAGE OCCLUSION, PFO/ASD/VSD/PDA CLOSURE, ALCOHOL ABLATION OF CARDIAC TISSUE, EMBOLIZATION OF CORONARY FISTULAE AND ABNORMAL VASCULAR CONNECTIONS IN THE HEART.
- (aa) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or physiological problems in the heart.
- (bb) “THERAPEUTIC CARDIAC CATHETERIZATION SESSION” MAY INCLUDE: PCI (ELECTIVE, EMERGENT), PERICARDIOCENTESIS, PERMANENT PACEMAKER IMPLANTATION, ICD IMPLANTATION (ENDOVASCULAR OR SUBCUTANEOUS), PACEMAKER OR ICD GENERATOR CHANGE, PACEMAKER OR ICD LEAD REVISION, CARDIAC ABLATION, AND/OR STRUCTURAL HEART PROCEDURE. THIS ALSO INCLUDES IMPLANTATION OF A CIRCULATORY SUPPORT DEVICE SUCH AS IABP, IMPELLA, ECMO OR TANDEMHEART WHERE THIS IS THE ONLY THERAPEUTIC PROCEDURE. WHEN PCI IS PERFORMED IN MORE THAN

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ONE CORONARY ARTERY DURING THE SAME SETTING, THIS IS COUNTED AS ONE SESSION.

- (cc) "THERAPEUTIC PERIPHERAL PROCEDURE" MEANS A THERAPEUTIC CATHETERIZATION PROCEDURE TO RESOLVE ANATOMIC AND/OR PHYSIOLOGIC PROBLEMS IN THE ARTERIAL OR VENOUS CIRCULATION (EXCLUDING THE HEART). PROCEDURES MAY INCLUDE PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA), ATHERECTOMY, DRUG ELUTING BALLOON, LASER, STENT IMPLANTATION, IVC FILTER IMPLANTATION OR RETRIEVAL, CATHETER-DIRECTED ULTRASOUND/THROMBOLYSIS, AND THROMBECTOMY.
- (dd) "THERAPEUTIC PERIPHERAL SESSION" MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE THERAPEUTIC PERIPHERAL PROCEDURES IN A CARDIAC CATHETERIZATION LABORATORY.
- (ee) "THERAPEUTIC PEDIATRIC/CONGENITAL CARDIAC CATHETERIZATION SESSION" MAY INCLUDE: STRUCTURAL HEART PROCEDURE (AS LISTED ABOVE), PULMONARY ARTERY ANGIOPLASTY/STENT IMPLANTATION, PULMONARY VALVE PERFORATION, ANGIOPLASTY/STENT IMPLANTATION FOR AORTIC COARCTATION, CARDIAC ABLATION, PACEMAKER/ICD IMPLANTATION, AND PCI.

- Section 5(3) - Added language to replace a cardiac catheterization service to a new site simultaneously with an open heart surgery service. (This language will only apply to those cardiac catheterization services that are being replaced simultaneously with an open heart surgery service. An open heart surgery service must have a diagnostic and therapeutic cardiac catheterization service.)
- Section 10(2) – Project delivery requirements have been updated.
  - (d) EACH PHYSICIAN CREDENTIALED BY A HOSPITAL TO PERFORM DIAGNOSTIC LEFT-HEART CATHETERIZATION AND/OR CORONARY ANGIOGRAPHY MUST PERFORM, AS THE PRIMARY OPERATOR, AN AVERAGE OF AT LEAST 50 DIAGNOSTIC CARDIAC CATHETERIZATION SESSIONS INVOLVING A LEFT-HEART CATHETERIZATION OR CORONARY ANGIOGRAPHY PER YEAR AVERAGED OVER THE MOST RECENT 2 YEARS STARTING IN THE SECOND 12 MONTHS AFTER BEING CREDENTIALED. THIS TWO YEAR AVERAGE WILL BE EVALUATED ON A ROLLING BASIS ANNUALLY THEREAFTER. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS A CARDIAC CATHETERIZATION SESSION IN WHICH THAT PHYSICIAN PERFORMED, AS THE PRIMARY OPERATOR, AT LEAST ONE LEFT-HEART CATHETERIZATION OR CORONARY ANGIOGRAPHY, IN ANY COMBINATION OF HOSPITALS. PHYSICIANS FALLING BELOW THIS VOLUME REQUIREMENT MUST BE PLACED ON A FOCUSED PROFESSIONAL PRACTICE EVALUATION (FPPE) PLAN, WHICH MUST INCLUDE AN INDEPENDENT REVIEW OF ALL DIAGNOSTIC CARDIAC CATHETERIZATION SESSIONS BY AN APPROPRIATE DESIGNEE, TO ENSURE QUALITY OUTCOMES ARE MAINTAINED. IN THE EVENT A PHYSICIAN DOES NOT PERFORM CARDIAC CATHETERIZATION PROCEDURES ON A TEMPORARY OR PERMANENT BASIS FOR A PERIOD OF 3 MONTHS OR MORE, THE PHYSICIAN DIAGNOSTIC PROCEDURE VOLUME WILL BE ANNUALIZED ON THE 24 MONTH PERIOD PRECEDING THE ABSENCE. WHEN A DIAGNOSTIC CARDIAC CATHETERIZATION SESSION AND AD HOC THERAPEUTIC CARDIAC CATHETERIZATION SESSION ARE PERFORMED TOGETHER, DIAGNOSTIC AND THERAPEUTIC SESSIONS ARE COUNTED SEPARATELY FOR THE PURPOSES OF THIS SUBSECTION. IF A PHYSICIAN IS DOING RIGHT HEART ONLY PROCEDURES, THEN THEY ARE NOT REQUIRED TO MEET THIS VOLUME

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REQUIREMENT. PHYSICIANS WHO ARE CREDENTIALED BY A HOSPITAL TO PERFORM ADULT THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES ARE NOT REQUIRED TO MEET THE VOLUME REQUIREMENT FOR DIAGNOSTIC CARDIAC CATHETERIZATION SESSIONS.

- (e) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization procedures shall perform, as the primary operator, aN AVERAGE of AT LEAST 50 adult therapeutic cardiac catheterization SESSIONS per year AVERAGED OVER THE MOST RECENT TWO YEARS STARTING in the second 12 months after being credentialed. THIS TWO-YEAR AVERAGE WILL BE EVALUATED ON A ROLLING BASIS annually thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization SESSIONS performed by that physician in any combination of hospitals. PHYSICIANS FALLING BELOW THIS VOLUME REQUIREMENT MUST BE PLACED ON A FOCUSED PROFESSIONAL PRACTICE EVALUATION (FPPE) PLAN, WHICH MUST INCLUDE AN INDEPENDENT REVIEW OF ALL THERAPEUTIC CARDIAC CATHETERIZATION SESSIONS BY AN APPROPRIATE DESIGNEE, TO ENSURE QUALITY OUTCOMES ARE MAINTAINED. IN THE EVENT A PHYSICIAN DOES NOT PERFORM CARDIAC CATHETERIZATION PROCEDURES ON A TEMPORARY OR PERMANENT BASIS FOR A PERIOD OF 3 MONTHS OR MORE, THE PHYSICIAN THERAPEUTIC PROCEDURE VOLUME WILL BE ANNUALIZED ON THE 24-MONTH PERIOD PRECEDING THE ABSENCE. WHEN A DIAGNOSTIC CARDIAC CATHETERIZATION SESSION AND AD HOC THERAPEUTIC CARDIAC CATHETERIZATION SESSION ARE PERFORMED TOGETHER, DIAGNOSTIC AND THERAPEUTIC SESSIONS ARE COUNTED SEPARATELY FOR THE PURPOSES OF THIS SUBSECTION (THIS INCLUDES INTERVENTIONAL CARDIOLOGISTS AND ELECTROPHYSIOLOGISTS). FOR INTERVENTIONAL CARDIOLOGISTS, THE THERAPEUTIC SESSION VOLUME EXCLUDES PACEMAKER AND ICD IMPLANTATION. FOR ELECTROPHYSIOLOGISTS, PACEMAKER AND ICD IMPLANTS PERFORMED IN AN OPERATING ROOM MAY ALSO BE COUNTED TOWARD THE PHYSICIAN THERAPEUTIC VOLUME.
- (f) Each physician credentialed by a hospital to perform pediatric/CONGENITAL cardiac catheterizations shall perform, as the primary operator, aN AVERAGE of AT LEAST 50 pediatric/CONGENITAL cardiac catheterization SESSIONS per year AVERAGED OVER THE MOST RECENT 2 YEARS STARTING in the second 12 months after being credentialed. THIS TWO-YEAR AVERAGE WILL BE EVALUATED ON A ROLLING BASIS and annually thereafter. The annual case load for a physician means pediatric/CONGENITAL cardiac catheterization SESSIONS performed by that physician in any combination of hospitals. PHYSICIANS FALLING BELOW THIS VOLUME REQUIREMENT MUST BE PLACED ON A FOCUSED PROFESSIONAL PRACTICE EVALUATION (FPPE) PLAN, WHICH MUST INCLUDE AN INDEPENDENT REVIEW OF ALL CARDIAC CATHETERIZATION SESSIONS BY AN APPROPRIATE DESIGNEE, TO ENSURE QUALITY OUTCOMES ARE MAINTAINED. IN THE EVENT A PHYSICIAN DOES NOT PERFORM CARDIAC CATHETERIZATION PROCEDURES ON A TEMPORARY OR PERMANENT BASIS FOR A PERIOD OF 3 MONTHS OR MORE, THE PHYSICIAN THERAPEUTIC PROCEDURE VOLUME WILL BE ANNUALIZED ON THE 24 MONTH PERIOD PRECEDING THE ABSENCE.
- (g) An adult diagnostic cardiac catheterization service shall have a minimum of two appropriately trained physicians on its active hospital staff MEETING THE FOLLOWING CRITERIA:
- (i) are trained consistent with the recommendations of the American College of Cardiology;
- (ii) are credentialed by the hospital to perform adult diagnostic cardiac

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catheterizations; and
- (iii) have performed a minimum of 100 adult diagnostic cardiac catheterization SESSIONS in the preceding 12 months. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS A CARDIAC CATHETERIZATION SESSION IN WHICH THAT PHYSICIAN PERFORMED, AS THE PRIMARY OPERATOR, AT LEAST ONE DIAGNOSTIC CARDIAC CATHETERIZATION, IN ANY COMBINATION OF HOSPITALS.
- (h) An adult therapeutic cardiac catheterization service shall have a minimum of two appropriately trained physicians on its active hospital staff MEETING THE FOLLOWING CRITERIA:
- (i) are trained consistent with the recommendations of the American College of Cardiology;
- (ii) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and
- (iii) have performed a minimum of 50 adult therapeutic cardiac catheterization procedures SESSIONS in the preceding 12 months. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS A CARDIAC CATHETERIZATION SESSION IN WHICH THAT PHYSICIAN PERFORMED, AS THE PRIMARY OPERATOR, AT LEAST ONE THERAPEUTIC CARDIAC CATHETERIZATION, IN ANY COMBINATION OF HOSPITALS.
- (i) A pediatric/CONGENITAL cardiac catheterization service shall have AT LEAST ONE physician on its active hospital staff MEETING THE FOLLOWING CRITERIA:

- Section 10(5) – Language has been updated to exclude patients with cardiogenic shock.
- Section 10(5)(f) – Modified language to make it applicable to only those catheterization labs providing primary PCI services without on-site OHS service and for catheterization labs providing elective PCI services without on-site OHS service.
- Section 10(5)(i) – Modified language for clarity.
- Section 11 – Updated procedure type, procedure equivalent, and added a description for the procedure type.
- Removed Appendix B as it's no longer needed given the revised definition for "pediatric/congenital cardiac catheterization service."
- Other technical edits.

Open HeartSurgery (OHS) Services: The revisions to the CON Review Standards for OHS Services include the following and became effective December 26, 2018:

- Updated the Department name throughout the document.
- Added language under new Section 4 – Requirements to replace an existing OHS Service. This language will not increase the number of OHS services in the state, instead it will allow current OHS providers to replace their service to a new location and discontinue service at the previous location. This language is consistent with language in other CON review standards.
  - (i) A pediatric/CONGENITAL cardiac catheterization service shall have AT LEAST ONE physician on its active hospital staff MEETING THE FOLLOWING CRITERIA:
  - SEC. 4. REPLACE AN EXISTING ADULT OR PEDIATRIC OHS SERVICE MEANS RELOCATING AN EXISTING ADULT OR PEDIATRIC OHS SERVICE TO A NEW GEOGRAPHIC LOCATION OF AN EXISTING LICENSED HOSPITAL. THE TERM DOES NOT INCLUDE THE REPLACEMENT OF AN EXISTING OHS SERVICE AT THE SAME SITE. AN APPLICANT REQUESTING TO REPLACE AN EXISTING OHS SERVICE SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.

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- (1) AN APPLICANT PROPOSING TO REPLACE AN EXISTING OHS SERVICE SHALL DEMONSTRATE THE FOLLOWING:
- (a) THE EXISTING OHS 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 A HOSPITAL THAT IS OWNED BY, IS UNDER COMMON CONTROL OF, OR HAS A COMMON PARENT AS THE APPLICANT HOSPITAL.
- (c) THE APPLICANT IS REPLACING THE OHS SERVICE SIMULTANEOUSLY WITH REPLACEMENT OF ITS CARDIAC CATHETERIZATION SERVICE(S) AT THE SAME LOCATION.
- (d) THE PROPOSED NEW SITE IS WITHIN THE SAME PLANNING AREA OF THE SITE AT WHICH THE EXISTING OHS SERVICE IS LOCATED AND WITHIN 5 MILES OF THE EXISTING OHS SERVICE LOCATION IF LOCATED IN A METROPOLITAN STATISTICAL AREA COUNTY, OR WITHIN 10 MILES OF THE EXISTING OHS SERVICE LOCATION IF LOCATED IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.
- (e) THE EXISTING OHS SERVICE TO BE RELOCATED PERFORMED AT LEAST THE APPLICABLE MINIMUM NUMBER OF OPEN HEART SURGICAL CASES SET FORTH IN SECTION 8 AS OF THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT UNLESS THE OHS SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF THE ENTIRE HOSPITAL TO A NEW GEOGRAPHIC SITE.
- (f) THE CARDIAC CATHETERIZATION AND OHS SERVICES SHALL CEASE OPERATION AT THE ORIGINAL SITE PRIOR TO BEGINNING OPERATION AT THE NEW SITE.

- Other technical edits.

Megavoltage Radiation Therapy (MRT) Services/Units: The revisions to the CON Review Standards for MRT Services/Units include the following and became effective on September 12, 2019:

- Updated the Department name throughout the document.
- Changed “dedicated stereotactic radiosurgery unit” to “dedicated stereotactic radiosurgery/stereotactic body radiation therapy (SRS/SBRT)” throughout the document.
- Section 10: Revised the weights and added additional factors and definitions for MR-guided real time tracking radiation w/o adaptive, MR-guided real time tracking radiation with adaptive, patient specific QA for IMRT, and patient specific QA for SRS/SBRT.
- Section 11(4): Reduced the maintenance volume for non-special MRT units from 8,000 ETVs annually to 4,000 ETVs annually.

Psychiatric Beds and Services: The revisions to the CON Review Standards for Psychiatric Beds and Services include the following and became effective on May 24, 2019:

- Revised the requirements of Section 8 “Requirements for approval of an applicant proposing to relocate existing licensed inpatient psychiatric beds” to include an exception where a child/adolescent service can be created, as follows in subsection (6):
  - (6) The relocation of beds under this section shall not result in initiation of a new adult or child/adolescent service EXCEPT FOR AN EXISTING ADULT INPATIENT PSYCHIATRIC SERVICE REQUESTING TO INITIATE A CHILD/ADOLESCENT INPATIENT PSYCHIATRIC SERVICE IN AN OVERBEDDED CHILD/ADOLESCENT PLANNING AREA PURSUANT TO SECTION 9(11).

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- Added new language in Section 9 “Requirements for approval to increase beds” with a new subsection 11 as follows:
    - (11) AN APPLICANT PROPOSING TO INITIATE A NEW CHILD/ADOLESCENT PSYCHIATRIC SERVICE, AS THE RECEIVING LICENSED INPATIENT PSYCHIATRIC HOSPITAL OR UNIT UNDER SECTION 8(6), SHALL DEMONSTRATE THAT IT MEETS ALL OF THE REQUIREMENTS OF THIS SUBSECTION AND SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE BED NEED IF THE APPLICATION MEETS ALL OTHER APPLICABLE CON REVIEW STANDARDS AND AGREES AND ASSURES TO COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS.
    - (a) THE APPROVAL OF THE PROPOSED NEW INPATIENT PSYCHIATRIC BEDS SHALL NOT RESULT IN AN INCREASE IN THE NUMBER OF LICENSED INPATIENT PSYCHIATRIC BEDS IN THE PLANNING AREA.
    - (b) THE APPLICANT MEETS THE REQUIREMENTS OF SUBSECTIONS (4), (5), AND (6) ABOVE.
    - (c) THE APPLICANT IS REQUESTING A MINIMUM OF 10 CHILD/ADOLSCENT PSYCHIATRIC BEDS TO A MAXIMUM OF 20 BEDS.
    - (d) THE APPLICANT:
    - (i) IS RELATED THROUGH COMMON OWNERSHIP, IN WHOLE OR IN PART, OR THROUGH COMMON CONTROL, WITH AN ACUTE-CARE HOSPITAL THAT HAS AN EMERGENCY DEPARTMENT THAT PROVIDES 24-HOUR EMERGENCY CARE SERVICES AND WHERE CHILD/ADOLESCENT PATIENTS WITH A PSYCHIATRIC AND/OR DEVELOPMENTAL DISABILITY DIAGNOSIS PRESENT AT AN AVERAGE OF AT LEAST 100 VISITS PER YEAR FOR EACH OF THE THREE MOST RECENT YEARS IN WHICH THERE IS DATA VERIFIABLE BY THE DEPARTMENT; AND
    - (ii) HAS AN AGREEMENT WITH THE ACUTE-CARE HOSPITAL TO GIVE PRIMARY CONSIDERATION FOR ADMISSION OF CHILD/ADOLESCENT PATIENTS FROM THE ACUTE-CARE HOSPITAL’S EMERGENCY DEPARTMENT IN NEED OF AN INPATIENT PSYCHIATRIC HOSPITAL ADMISSION.
    - (iii) HAS A COLLABORATIVE AGREEMENT WITH AN EXISTING CHILD/ADOLESCENT PSYCHIATRIC HOSPITAL OR UNIT FOR CONSULTATION AND SUPPORTIVE SERVICES WITH A PROPOSED TERM OF NOT LESS THAN TWELVE MONTHS AFTER IMPLEMENTATION.
    - (e) THE PROPOSED SITE FOR THE NEW CHILD/ADOLESCENT BEDS HAS NOT PREVIOUSLY BEEN APPROVED FOR BEDS UNDER THIS SUB-SECTION.
    - (f) THE PROPOSED PROJECT TO ADD NEW CHILD ADOLESCENT PSYCHIATRIC BEDS, UNDER THIS SUBSECTION, SHALL CONSTITUTE A CHANGE IN BED CAPACITY UNDER SECTION 1(2) OF THESE STANDARDS.
    - (g) APPLICANTS PROPOSING TO ADD NEW CHILD/ADOLESCENT PSYCHIATRIC BEDS UNDER THIS SUBSECTION SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW.

During FY2020, the CON Commission revised the review standards for Immune Effector Cell Therapy (IECT) Services, Nursing Home and Hospital Long-Term-Care Unit (NH-HLTCU) Beds, Psychiatric Beds and Services, Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services.

Immune Effector Cell Therapy (IECT) Services: The Commission took final action on CON Review Standards for IECT Services at its September 19, 2019 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period. The legislature took negative action and the standards did not go into effect.

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Psychiatric Beds and Services: The revisions to the CON Review Standards for Psychiatric Beds and Services include the following and became effective on November 12, 2019:

- Section 2: The definition of "base year" was removed as it's no longer used in the standard.
- Section 3: A new bed need methodology. There is now one methodology for both adult and child/adolescent beds. The methodology incorporates a time series approach to predict future patient days and normative approach to distribute those patient days to the Health Service Areas (HSA).
- Old Section 5 was removed as it's no longer needed.
- Added minimum occupancy requirements in last 12-months prior to application submission, as in hospital beds standards, for the existing psych hospital/unit before a new entity can acquire the facility, replace the facility, or relocate beds. Appropriate sections updated accordingly.
- New Section 8 was revised for clarity.
- New Section 11 includes revised comparative review requirements to include more emphasis on access for indigent and high acuity populations. Formulas for comparative review have been simplified.
- Appendices A and B were removed as they're no longer needed.
- The Addendum was revised as follows:
    - Added high acuity psychiatric units.
    - Increased the percentage of the state bed need formula to increase the number of special pool beds.
    - Revised the standard for med-psych units to allow freestanding psychiatric units with collaborative agreements with medical service hospitals.
- Other technical edits.

Urinary Extracorporeal Shock Wave Lithotripsy: The revisions to the CON Review Standards for UESWL Services include the following and became effective on November 12, 2019:

- Revised the requirements for fixed lithotripsy units from 1,000 to 500 procedures per unit annually for the minimum required volume in the project delivery requirements, as well as replacement and acquisition, to be consistent with the newly approved language for initiation.
- Section 7(1)(c): For clarity, added the following language "A SEPARATE CON APPLICATION HAS BEEN SUBMITTED BY THE CSC AND EACH PROPOSED HOST SITE."
- Section 7(3): For clarity, added the following language "THE NORMAL ROUTE SCHEDULE, THE PROCEDURES FOR HANDLING EMERGENCY SITUATIONS, AND COPIES OF ALL POTENTIAL CONTRACTS RELATED TO THE MOBILE UESWL SERVICE AND ITS UNIT(S) SHALL BE INCLUDED IN THE CON APPLICATION SUBMITTED BY THE CENTRAL SERVICE COORDINATOR OR THE APPLICANT HOST SITE."
- Other technical edits.

NH-HLTCU: The revisions to the CON Review Standards for NH-HLTCU include the following and became effective on September 3, 2020:

- Section 6(1)(e): Added language that requires a planning area to have an occupancy rate of 85% or more to be able to begin operation of a new NH-HLTCU or to increase the number of beds at an existing licensed NH-HLTCU. This will help to ensure that beds go to the areas where needed as the standard advisory committee (SAC) continues to work on an improved bed need methodology.

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- Section 6(2)(f): Added language that requires a planning area to have an occupancy rate of 85% or more to be able to begin operation of a new NH-HLTCU or to increase the number of beds at an existing licensed NH-HLTCU pursuant to the new design model. This will help to ensure that beds go to the areas where needed as the SAC continues to work on an improved bed need methodology.
- Section 14(1): Updated dates.

The following review standards were reviewed with an anticipated completion in FY2021:

Computed Tomography (CT) Scanner Services: Proposed action was taken by the Commission at its June 18, 2020 meeting. The standards were submitted to the joint legislative committee (JLC) and a Public Hearing was held. The Commission took final action at its September 17, 2020 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period. Standards will become effective in FY2021.

Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services: Proposed action was taken by the Commission at its September 17, 2020 meeting. The standards were submitted to the JLC and a Public Hearing was held. The Commission took final action at its December 10, 2020 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period. Standards will become effective in FY2021.

NH-HLTCU Services: Proposed action was taken by the Commission at its September 17, 2020 meeting. The standards were submitted to the JLC and a Public Hearing was held. The Commission took final action at its December 10, 2020 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period. Standards will become effective in FY2021.

Cardiac Catheterization Services: The standards are being reviewed by a SAC.

Hospital Beds: The standards are scheduled to be reviewed by a SAC.

Positron Emission Tomography (PET) Scanner Services: The standards are scheduled to be reviewed by a workgroup.

Magnetic Resonance Imaging (MRI) Services: The standards are scheduled to be reviewed by a workgroup.

September 8, 2020

Dear CON Commission,

This letter is to provide you with an update on the status of the Standard Advisory Committee (SAC) for cardiac catheterization services in the state of Michigan. As you know, the SAC convened and conducted its first meeting on August 27, 2020. At that meeting, the SAC members were introduced, a basic overview of the CON was provided, and the charge was reviewed. The remainder of the meeting was spent developing an agenda and timeline for discussing the specific items listed in the charge. Accordingly, the SAC will discuss charge items 1 through 3 at the SAC meeting on September 24, 2020. Charge items 6 through 8, which focus on electrophysiology issues, will be discussed at the SAC meeting on October 22, 2020. The remaining charges, most of which deal with issues surrounding the performance of cardiac catheterization and percutaneous coronary intervention in ambulatory surgical centers, will be discussed at the remaining meetings. We are currently on scheduled to provide a recommendation to the CON commission within the allotted 6-month time frame. Should you have any questions or concerns, please not hesitate to contact me directly.

Sincerely,

Ryan D. Madder, MD, FACC

CERTIFICATE OF NEED

3rd Quarter Compliance Report to the CON Commission

October 1, 2019 through September 30, 2020 (FY 2020)

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	55	185
Approved projects contacted on or before anniversary date	37	118
Approved projects completed on or before 1-year follow up	67%	
CON approvals expired	17	42
Total follow up correspondence sent	185	705
Total approved projects still ongoing	343	

Compliance: In accordance with Section 22247 and Rule 9419, the Department performs compliance checks on approved and operational Certificates of Need to determine if projects have been implemented, or if other applicable requirements have been met, in accordance with Part 222 of the Code.

- The Department is conducting statewide compliance reviews for Surgical Services and Air Ambulance (Helicopter) services, utilizing the 2018 CON Annual Survey data. The Department completed the process of evaluating annual survey data, review standard requirements, facilities' responses to compliance questionnaire, and CON approved facilities for these selected services and identified the facilities for compliance investigations.

  The statewide compliance review for Air Ambulance services is complete without any further actions needed. The Department is in the process of setting up conference calls and contacting the facilities for Surgical Services for further discussions. The findings of the statewide compliance review will be reported to the CON Commission at a later date.

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

CERTIFICATE OF NEED

3rd Quarter Program Activity Report to the CON Commission

October 1, 2019 through September 30, 2020 (FY 2020)

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	105	N/A	339	N/A
Letters of Intent Processed within 15 days	105	100%	337	99%
Letters of Intent Processed Online	105	100%	339	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	90	N/A	292	N/A
Applications Processed within 15 Days	90	100%	292	100%
Applications Incomplete/More Information Needed	21	23%	106	36%
Applications Filed Online*	85	94%	240	82%
Application Fees Received Online*	11	12%	47	16%

** 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%	97	100%
Substantive Applications	30	100%	61	100%
Comparative Applications	9	100%	13	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	61	100%	102	100%
Decisions Issued within 10 workings Days	61	100%	102	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.

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	17	100%	60	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	57	N/A	185	N/A
FOIA Requests Processed on Time *	57	100%	185	100%
Number of Applications Viewed Onsite	0	N/A	0	N/A

FOIA – Freedom of Information Act.

**Request processed within 5 days or an extension filed.*

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

Certificate of Need (CON) Statewide Compliance Review

Air Ambulance Services

As part of the Air Ambulance services statewide compliance review, the Department reviewed 11 facilities (2 hospital based and 9 freestanding Air Ambulance providers) that offer Air Ambulance service, based on the reported data in the 2018 and 2019 CON Annual Surveys. The Air Ambulance services for those facilities were approved under 2 different review standards, the oldest dating back to August 12, 2010.

After reviewing the Air Ambulance data in the 2018 and 2019 CON Annual Surveys and responses to Air Ambulance questionnaire, the Department sent emails to confirm the compliance findings with the facilities. The Department's findings resulted in all facilities complying with all review standard requirements.

The table below shows the breakdown of all facilities under each Air Ambulance standard:

August 12, 2010	3
June 2, 2014	8

Review Standards Effective Date	No. of Air Ambulance Providers
August 12, 2010	2
June 2, 2014	0

Review Standards Effective Date	No. of Air Ambulance Providers
August 12, 2010	1
June 2, 2014	8

The table below shows the breakdown of the facilities by Health Service Area (HSA):

FACILITY NAME	STANDARDS	COUNTY	COUNTY DESIGNATION	STATUS
HSA 1: SOUTH EAST MICHIGAN				
Facility 1	August 12, 2010	Washtenaw	Metropolitan	Met All Requirements
Facility 2	August 12, 2010	Oakland	Metropolitan	Met All Requirements
HSA 2: MID-SOUTH MICHIGAN				
N/A				
HSA 3: SOUTHWEST MICHIGAN				
Facility 3	June 2, 2014	Kalamazoo	Metropolitan	Met All Requirements

STATE OF MICHIGAN
DEPARTMENT OF ATTORNEY GENERAL

DANA NESSEL
ATTORNEY GENERAL

M E M O R A N D U M

September 9, 2020

TO: James Falahee
CON Commission Chair

FROM: Rebecca Berels
Assistant Attorney General
Corporate Oversight Division

CC: Elizabeth Nagel
Joseph E. Potchen

RE: Legal Activity Report for the September 17, 2020 Commission Meeting

We are currently representing DHHS in sixteen pending cases in the Michigan Office of Administrative Hearings and Rules ("MOAHR").

1) *Beaumont Hospital – Oxford, v DHHS* (MOAHR Docket No.: 19-010768)

   On September 30, 2019, DHHS issued a proposed decision to disapprove William Beaumont Hospital's CON Application to initiate a new hospital in Limited Access Area #6. On July 14, 2020, the Administrative Law Judge issued a Proposal for Decision in the Department's favor. We are now awaiting the Director's Final Order on the proposed decision.

2) *Kalamazoo Psych Operator, LLC v DHHS* (MOAHR Docket No.: 20-003167)

   Kalamazoo Psych Operator appealed the denial of its CON application for psychiatric beds as part of Comparative Review Group 95-058. Kalamazoo Psych Operator voluntarily withdrew its appeal on September 3, 2020.

3) Fourteen Nursing Home Comparative Review Appeals: *Trilogy Healthcare of Portage LLC & Medilodge of Kalamazoo v DHHS* (MOAHR Docket Nos. 20-004321 and 20-004921 CON (consolidated)); *Regency at Grand Rapids LLC, Regency at Celebration LLC, Northern Kent Nursing Center & Kent Nursing Center v DHHS* (MOAHR Docket Nos. 20-004906, 20-004908, 20-004909, 20-004911 CON (consolidated)); *Livingston Nursing Center & Pinckney Nursing*

Center v DHHS (MOAHR Docket Nos. 20-004950 and 20-004951 CON (consolidated)); *Fountain View of Monroe v DHHS* (MOAHR Docket No. 20-004952 CON (consolidated)); *Novi Nursing Center, Clarkston Nursing Center, Oxford Nursing Center, Regency on the Lake-Novi LLC, Bloomfield Orchard Villa v DHHS* (MOAHR Docket Nos. 20-004913, 20-004914, 20-004916, 20-004917, 20-004919 CON (consolidated))

Fourteen CON Applicants within five Comparative Review Groups (Kalamazoo County, 95-0263; Kent County, 95-0261; Livingston County, 95-0264; Monroe County, 95-0265; Oakland County, 95-0262) appealed the denial of their CON applications to begin operation of new nursing homes. On September 3, 2020, a revised NH/HLTCU Review Standard took effect, thus necessitating a remand to DHHS for issuance of a new proposed decision under the revised Standard. As such, we filed motions for remand in each of the consolidated cases, which are awaiting decision. Meanwhile, telephone prehearing conferences have been scheduled in each case.

In addition to these administrative matters, we are representing DHHS in two additional Court actions relating to Beaumont – Oxford's CON Application (see first entry in MOAHR list above).

1) *William Beaumont Hospital v Certificate of Need Commission & DHHS*; Court of Claims Case No. 19-000183-MZ; Court of Appeals Case No. 352568

   In the Court of Claims, Beaumont filed a request for declaratory judgment related to the interpretation of Section 6(5)(g)(i) of the Hospital Bed Review Standards and for injunctive relief preventing the Commission from adopting new Standards related to Limited Access Areas while Beaumont's administrative appeal is pending. The Court of Claims granted summary disposition for DHHS and the Commission. Beaumont filed a Claim of Appeal with the Court of Appeals.

   In the Court of Appeals, Beaumont filed its brief, requesting oral argument, on July 6, 2020. We filed our response, declining to request oral argument, on August 10, 2020, and Beaumont filed a reply on August 31, 2020. The matter remains pending in the Court of Appeals for either scheduling of oral argument or issuance of a decision.

2) *William Beaumont Hospital v DHHS*; Case No. 19-000836-AA

   In the Ingham Circuit Court, Beaumont filed an appeal of the Department's October 18, 2019 denial of a request for declaratory ruling on the interpretation of Section 6(5)(g)(i) of the Hospital Bed Review Standards and

a request for declaratory judgment. This matter is pending a decision on our motion to dismiss.

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

RAB/

FACILITY NAME	STANDARDS	COUNTY	COUNTY DESIGNATION	STATUS
HSA 4: WEST MICHIGAN				
Facility 4	August 12, 2010	Kent	Metropolitan	Met All Requirements
HSA 5: GENESEE-LAPEER-SHIAWASSEE				
N/A				
HSA 6: EAST CENTRAL MICHIGAN				
Facility 5	June 2, 2014	Saginaw	Metropolitan	Met All Requirements
Facility 6	June 2, 2014	Saginaw	Metropolitan	Met All Requirements
HSA 7: NORTHERN LOWER MICHIGAN				
Facility 7	June 2, 2014	Grand Traverse	Micropolitan	Met All Requirements
HSA 8: UPPER PENINSULA				
Facility 8	June 2, 2014	Delta	Micropolitan	Met All Requirements
OUT OF STATE				
Facility 9	June 2, 2014	Toledo, OH	Out of State	Met All Requirements
Facility 10	June 2, 2014	Toledo, OH	Out of State	Met All Requirements
Facility 11	June 2, 2014	South Bend, IN	Out of State	Met All Requirements

DRAFT Certificate of Need (CON) Commission Work Plan

Attachment O

	2020											
	January	February	March	April	May	June	July	August	September	October	November	December
Commission Meetings	Special Meeting		Meeting Cancelled			Meeting			Meeting			Meeting
Bone Marrow Transplantation (BMT) Services										Public Comment Period		
Cardiac Catheterization Services	Discussion/ Report		SAC Nomination & Selection Period					CCSAC Mtg.	CCSAC Mtg.	CCSAC Mtg.	CCSAC Mtg.	CCSAC Mtg.
Computed Tomography (CT) Scanner Services	CT Workgroup Mtg.	CT Workgroup Mtg.				Report/Draft Language Presented/ Potential Proposed Action	Public Hearing		Report/ Final Action			
Heart/Lung and Liver (HLL) Transplantation Services										Public Comment Period		
Hospital Beds	Discussion/ Report							Sac Nomination & Selection Period			HBSAC Mtg.	HBSAC Mtg.
Magnetic Resonance Imaging (MRI) Services	Discussion/ Report									Public Comment Period		
Neonatal Intensive Care Services/Beds (NICU)	NICU Workgroup Mtg.		NICU Workgroup Mtg.		NICU Workgroup Mtg.	NICU Workgroup Mtg.	NICU Workgroup Mtg.	NICU Workgroup Mtg.	Report/Draft Language Presented/ Potential Proposed Action	Public Hearing		
Nursing Home and HLTCU Beds and Addendum (NH-HLTCU)	Interim Report to Commission/ Draft Language Presented/ Proposed Action; NH-HLTCU SAC Mtg.		Public Hearing; NH-HLTCU SAC Mtg.			NH-HLTCU SAC Mtg.	Report/Final Action; NH-HLTCU SAC Mtg.		Report/Draft Language Presented/ Potential Proposed Action	Public Hearing		Report/Final Action
Positron Emission Tomography (PET) Scanner Services	Discussion/ Report					Presentation						
Psychiatric Beds and Services										Public Comment Period		

New Medical Technology Standing Committee	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring
2-year Report to Joint Legislative Committee (JLC) – 1/1/21									Review Draft Report			Approve Report

For Approval September 17, 2020.

The CON Commission may revise this work plan at each meeting. For information about the CON Commission work plan or how to be notified of CON Commission meetings, contact the Michigan Department of Health and Human Services (MDHHS) at, 517-335-6708 or www.michigan.gov/con**.**

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

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	June 2, 2014	2022
Bone Marrow Transplantation Services	September 29, 2014	2021
Cardiac Catheterization Services	December 26, 2018	2020
Computed Tomography (CT) Scanner Services	December 9, 2016	2022
Heart/Lung and Liver Transplantation Services	September 28, 2012	2021
Hospital Beds	November 28, 2018	2020
Magnetic Resonance Imaging (MRI) Services	October 21, 2016	2021
Megavoltage Radiation Therapy (MRT) Services/Units	September 12, 2019	2023
Neonatal Intensive Care Services/Beds (NICU)	December 9, 2016	2022
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	September 3, 2020	2022
Open Heart Surgery Services	December 26, 2018	2023
Positron Emission Tomography (PET) Scanner Services	September 14, 2015	2020
Psychiatric Beds and Services	November 12, 2019	2021
Surgical Services	November 17, 2017	2023
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	November 12, 2019	2022

*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.