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

Thursday June 12, 2014

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

APPROVED MINUTES

I. Call to Order & Introductions

Chairperson Keshishian called the meeting to order @ 9:36 a.m.

A. Members Present:

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

B. Members Absent

Gail J. Clarkson, RN
Gay L. Landstrom, RN

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Community Health Staff Present:

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

II. Review of Agenda

Motion by Commissioner Gayney, seconded by Commissioner Tomatis, to approve the agenda as modified by adding Public Comment to Item IX (Commission Bylaws- Article VII(B)(3)(d)) of the agenda. Motion Carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of March 18, 2014

Motion by Commissioner Brooks-Williams, seconded by Commissioner Cowling, to approve the minutes of March 18, 2014 as presented. Motion Carried.

V. Bone Marrow Transplantation (BMT) Services- April 30, 2014 Public Comment Period Summary & Report

Ms. Rogers gave a brief overview of the public hearing summary and the department's recommendations (see Attachment A).

A. Public comment

None.

B. Commission Discussion

No discussion.

C. Commission Final Action

Motion by Commissioner Falahee, seconded by Commissioner Cowling, to approve and move these standards (see Attachment B) forward to the Joint Legislative Committee (JLC) and governor for the 45-day review period. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

VI. Nursing Home and Hospital Long-Term Unit (NH-HLTCU) Beds- Workgroup Final Report

Ms. Messick gave the final report from the NH-HLTCU workgroup (see Attachment C).

A. Public Comment

Pat Anderson, HCAM (see Attachment D)

Pat Anderson (for David Stobb), Ciena Healthcare (see Attachment E)

B. Commission Discussion

Discussion followed.

C. Commission Proposed Action

Motion by Commissioner Tomatis, seconded by Commissioner Gayney, to approve the language as presented by the workgroup (see Attachment F), to send the language to public hearing and the JLC for review. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

Motion by Commissioner Falahee, seconded by Commissioner Cowling to review the additional findings from the workgroup that were not part of the specific charge, submit to the Commission appropriate language if the Department deems the issues are appropriate. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstained.

VII. Hospital beds- Status Report

Ms. Rogers gave a brief background update.

Commissioner Brooks-Williams stated a potential conflict of interest.

Karen Kippen, Henry Ford Health Systems (HFHS) gave a brief presentation and overview of the definition of contiguous site (see Attachment G).

A. Public Comment

None.

B. Commission Discussion

Discussion followed.

Motion by Commissioner Gayney, seconded by Commissioner Falahee, to have the Department evaluate the language presented by HFHS (see Attachment G) to post pone further discussion until the September 25, 2014 CON Commission meeting. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstained.

VIII. Computed Tomography (CT) Scanner Services, Hospital Beds, Magnetic Resonance Imaging (MRI) Services, Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursery Services, Surgical Services, and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL)

Services- Rural, Micropolitan Statistical Area, and Metropolitan Statistical Area Michigan Counties Update

Ms. Rogers gave a brief overview of the proposed changes, and recommended removal of Hospital Beds from Proposed Action at this time.

A. Public Comment

Amy Barkholz, Michigan Hospital Association (MHA)

B. Commission Discussion

None.

C. Commission Proposed Action on Each Standard Separately

Motion by Vice-chairperson Mukherji, seconded by Commissioner Cowling, to approve the CT scanner services language(see Attachment H) as presented by the department, and to send the language to public hearing and the JLC for review. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

Motion by Vice-chairperson Mukherji, seconded by Commissioner Cowling, to approve the MRI services language (see Attachment I) as presented by the department, and to send the language to public hearing and the JLC for review. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstained.

Motion by Commissioner Falahee, seconded by Commissioner Gayney, to approve the NICU and Special Newborn Nursing services language (see Attachment J) as presented by the department, and to send the language to public hearing and the JLC for review. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstained.

Motion by Commissioner Hughes, seconded by Commissioner Tomatis, to approve the Surgical Services language (see Attachment K) as presented by the department, to send the language to public hearing and the JLC for review. Motion Carried in a vote of 9-Yes, 0- No, and 0- Abstained.

Motion by Commissioner Kochin, seconded by Commissioner Brooks-Williams, to approve the UESWL services language (see Attachment L) as presented by the department, and to send the language to public hearing and the JLC for review. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstained.

IX. Commission Bylaws- Article VII(B)(3)(d)

Chairperson Keshishian gave a brief overview of this issue and stated he will work with the department to draft language.

A. Public Comment

None.

X. Legislative Report

Ms. Hertel gave a brief summary of recent legislative activity, including an update on the audit being conducted to measure the performance of the CON program within the department.

XI. Administrative Update

A. Planning and Access to Care

Ms. Nagel gave a brief update on the seating of the Megavoltage Radiation Therapy (MRT) Standard Advisory Committee (SAC) and the Cardiac Catheterization (CC) SAC.

B. CON Evaluation Section Update

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

   Ms. Bhattacharya gave a brief summary of the compliance report.

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

   Ms. Bhattacharya gave a brief summary of the quarterly performance report.

XII. Legal Activity Report

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

XIII. Future Meeting Dates- September 25, 2014, & December 11, 2014

XIV. Public Comment

None.

XV. Review of Commission Work Plan

Ms. Rogers gave a brief overview of the Work Plan (see Attachment P) including today's actions.

A. Commission Discussion

None.

B. Commission Action

Motion by Commissioner Cowling, seconded by Commissioner Tomatis to accept the work plan as presented. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstained.

XVI. Adjournment

Motion by Commissioner Gayney, seconded by Vice-chairperson Mukherji to adjourn the meeting at 11:46 a.m. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstained.

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

Date: May 20, 2014

TO: Brenda Rogers

FROM: Natalie Kellogg

RE: Summary of Public Hearing Comments on Bone Marrow Transplantation (BMT) Services

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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 BMT Services Standards at its March 18, 2014 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed BMT Services Standards on April 30, 2014. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was received from one organization and is summarized as follows:

Carol Christner, Karmanos Cancer Center

- Supports the BMT standards as written and initially approved by the CON Commission.
- Recommends the Commission take final action at the June 12, 2014 meeting on these standards.

Recommendations

The Department recommends that the Commission take final action to approve the language as presented at the June 12, 2014 meeting.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

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

Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval to initiate or acquire BMT services under Part 222 of the Code. BMT services are a covered clinical service pursuant to Part 222 of the Code. The Department shall use these standards in applying Section 22225(1) of the Code being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(C) of the Code, being Section 333.22225(2)(C) of the Michigan Compiled Laws.

(2) A BMT service listed on the Department inventory that is located at a hospital site and initially does not perform both allogeneic and autologous procedures shall not be required to obtain separate CON approval to begin performing both autologous and allogeneic BMT procedures.

(3) An existing BMT service that performs only adult procedures shall require separate CON approval in order to perform pediatric procedures. An existing BMT service that performs only pediatric procedures shall require separate CON approval in order to perform adult procedures.

Section 2. Definitions

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

(a) "Adult" means an individual age 18 or older.

(b) "Allogeneic" means transplantation between genetically non-identical individuals of the same species.

(c) "Autologous" means transplantation in which the donor and recipient are the same individual.

(d) "Bone marrow transplantation service" or "BMT service" means the transplantation of proliferating hematopoietic stem cells essential to the survival of a patient derived from the bone marrow, the peripheral circulation, cord blood, or any other source.

(e) "Cancer hospital" means a hospital that ~~has been approved~~IS ~~to participate in the Title XVIII (Medicare) program as a prospective payment system (PPS) exempt hospital in accordance with Section 1886 (d)(1)(B)(v) of the Social Security Act, as amended~~ A COMPREHENSIVE CANCER CENTER DESIGNATED BY THE NATIONAL CANCER INSTITUTE OR OPERATES A COMPREHENSIVE CANCER CENTER AS AN AFFILIATE OF A MICHIGAN UNIVERSITY THAT IS DESIGNATED AS A COMPREHENSIVE CANCER CENTER BY THE NATIONAL CANCER INSTITUTE.

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

(g) "Comparative group" means the applications that 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.

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

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

(j) "Department inventory of BMT services" means the list maintained by the Department of: (i) the bone marrow transplantation services operating pursuant to a valid CON issued under Part 222 or former Part 221; (ii) operating BMT services for which the operation of that service did not require a CON; and (iii) BMT services that are not yet operational but have a valid CON issued under Part 222. The list shall

inventory adult and pediatric services separately and shall specify the site at which the BMT service is authorized.

(k) "Existing BMT service," for purposes of Section 3(5) of these standards, means any of the following: (i) a BMT service listed on the Department inventory, (ii) a proposed BMT service under appeal from a final decision of the Department, or (iii) a proposed BMT service that is part of a completed application under Part 222 (other than the application under review) for which a proposed decision has been issued and which is pending final decision.

(l) "Health service area" or "HSA" means the geographic area set forth in Appendix A.

(m) "Initiate" or "implement" means the performance of the first transplant procedure. The term of an approved CON shall be 18 months or the extended period established by Rule 325.9403(2).

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

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

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

(q) "Pediatric" means any patient 20 years of age or less or any patient with congenital conditions or diseases for which BMT is a treatment.

(r) "Planning area" means:

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

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

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

(t) "Survival rate" means the rate calculated using the Kaplan-Meier technique and the following: (i) the date of transplantation (or, if more than one transplant is performed, the date of the first transplant) must be the starting date for calculation of the survival rate; (ii) for those dead, the date of death is used, if known. If the date of death is unknown, it must be assumed as 1 day after the date of the last ascertained survival; (iii) for those who have been ascertained as surviving within 60 days before the fiducial date (the point in time when the facility's survival rates are calculated and its experience is reported), survival is considered to be the date of the last ascertained survival, except for patients described in subsection (v); (iv) any patient who is not known to be dead, but whose survival cannot be ascertained to a date that is within 60 days before the fiducial date, must be considered as "lost to follow up" for the purposes of the survival rate calculation; (v) any patient transplanted between 61 and 120 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained for at least 60 days before the fiducial date. Any patient transplanted within 60 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained on the fiducial date; and (vi) the survival analyses must use the assumption that each patient in the "lost to follow up" category died 1 day after the last date of ascertained survival. However, an applicant may submit additional analyses that reflect each patient in the "lost to follow up" category as alive at the date of the last ascertained survival.

(u) “Tumor registry” means a manual or computerized data base containing information about all malignancies and only those that are diagnosed and/or treated at the applicant’s facility. The malignancies must be reportable to the Michigan Cancer Surveillance Program as required pursuant to Public Act 82 of 1984, as amended.

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

Section 3. Requirements to initiate a BMT service

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

(1) An applicant shall specify in the application whether the proposed service will perform either or both adult and pediatric BMT procedures.

(2) An applicant shall specify the licensed site at which the BMT service will be provided.

(3) An applicant proposing to initiate either an adult or pediatric BMT service shall demonstrate that the licensed site at which the transplants will be offered provides each of the following staff, services, and programs:

(a) operating rooms.

(b) continuous availability, on-site or physically connected, either immediate or on-call, of CT scanning, magnetic resonance imaging, ultrasound, angiography, and nuclear medicine services.

(c) dialysis.

(d) inpatient-outpatient social work.

(e) inpatient-outpatient psychiatry/psychology.

(f) clinical research.

(g) a microbiology and virology laboratory.

(h) a histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics, or an equivalent organization, either on-site or through written agreement.

(i) a hematopathology lab capable of performing cell phenotype analysis using flow cytometry.

(j) a clinical chemistry lab with the capability to monitor antibiotic and antineoplastic drug levels, available either on-site or through other arrangements that assure adequate availability.

(k) other support services, as necessary, such as physical therapy and rehabilitation medicine.

(l) continuous availability of anatomic and clinical pathology and laboratory services, including clinical chemistry, and immuno-suppressive drug monitoring.

(m) continuous availability of red cells, platelets, and other blood components.

(n) an active medical staff that includes, but is not limited to, the following board-certified or board-eligible specialists. For an applicant that is proposing to perform pediatric transplant procedures, these specialists shall be board-certified or board-eligible in the pediatric discipline of each specialty.

(i) anesthesiology.

(ii) cardiology.

(iii) critical care medicine.

(iv) gastroenterology.

(v) general surgery.

(vi) hematology.

(vii) infectious diseases.

(viii) nephrology.

(ix) neurology.

(x) oncology.

(xi) pathology, including blood banking experience.

(xii) pulmonary medicine.

(xiii) radiation oncology.
(xiv) radiology.
(xv) urology.

(o) One or more consulting physicians who are board-certified or board-eligible in each of the following specialties. For an applicant proposing to perform pediatric BMT procedures, these specialists shall have specific experience in the care of pediatric patients.

(i) dermatology.
(ii) immunology.
(iii) neurosurgery.
(iv) orthopedic surgery.

(4) An applicant must provide an implementation plan for the proposed BMT service. “Implementation plan" means a plan that documents how a proposed BMT service will be initiated within the time period specified in these standards or the CON rules. At a minimum, the implementation plan shall identify:

(a) each component or activity necessary to begin performing the proposed BMT service including, but not limited to, the development of physical plant requirements, such as an intensive care unit capable of treating immuno-suppressed patients, equipment acquisitions, and recruitment and employment of all physician and support staff;

(b) the time table for completing each component or activity specified in subsection (a); and

(c) if the applicant previously has been approved for a BMT service for which either the CON expired or the service did not perform a transplant procedure during any consecutive 12-month period, what changes have or will be made to ensure that the proposed service can be initiated and provided on a regular basis.

(5)(a) An applicant shall demonstrate that the number of existing adult BMT services does not exceed three (3) adult BMT services in planning area one identified in Section 2(1)(t)(i) or one (1) adult BMT service in planning area two identified in Section 2(1)(t)(ii) and that approval of the proposed application will not result in the total number of adult BMT services exceeding the need for each specific planning area.

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

(6)(a) An applicant proposing to initiate an adult BMT service shall project that at least 30 transplants, of which at least 10 are allogeneic transplant procedures, will be performed in the third 12-months of operation.

(b) An applicant proposing to initiate a pediatric BMT service shall project that at least 10 transplants, of which 5 are allogeneic transplant procedures, will be performed in the third 12-months of operation.

(c) An applicant proposing to initiate both an adult and a pediatric BMT service shall specify whether patients age 18-20 are included in the projection of adult procedures required pursuant to subsection (a) or the projection of pediatric procedures required pursuant to subsection (b). An applicant shall not include patients age 18-20 in both adult and pediatric projections required pursuant to subsections (a) and (b).

(7) An applicant shall provide megavoltage radiation therapy services, either on-site or physically connected, with a nominal beam energy of at least 6 MEV, including the capability to perform total body irradiation.

(8) An applicant shall demonstrate that the licensed site at which the proposed BMT service is proposed has an institutional review board.

(9) An applicant proposing to initiate a pediatric BMT service shall demonstrate that the licensed site at which the pediatric transplant procedures will be performed has each of the following:

(a) a designated pediatric inpatient oncology unit.

(b) a pediatric inpatient intensive care unit.

(c) membership status in either the Pediatric Oncology Group (POG) or the Children's Cancer Group (CCG).

(d) a pediatric tumor board that meets on a regularly scheduled basis.

(e) family support group services, provided either directly or through written agreements.

(f) a pediatric cancer program with the following staff:

(i) a director who is either a board-certified immunologist who has specific training and experience in BMT or a board-certified pediatric hematologist/oncologist.

(ii) nurses with training and experience in pediatric oncology.

(iii) social workers with training and experience in pediatric oncology.

(iv) pediatric psychologists.

(v) child life specialists.

(10)(a) An applicant proposing to initiate either a new adult or pediatric BMT service shall submit, in its application, a written consulting agreement with an existing BMT service. The written consulting agreement must be with an existing in-state or out-of-state Foundation for the Accreditation of Cellular Therapy (FACT) accredited transplant unit that performs both allogenic and autologous transplants for either adult and/or pediatrics. The terms of the agreement and the roles and responsibilities of both the existing and proposed service shall include at least the following:

(i) The term of the written consulting agreement is no less than 36 months after the proposed service begins to perform BMT procedures.

(ii) One or more representatives of the existing BMT service have been designated as staff responsible for carrying out the roles and responsibilities of the existing service.

(iii) The existing service shall evaluate and make recommendations to the proposed service on policies and procedures, including time tables, for at least each of the following:

(A) nursing services.

(B) infection control.

(C) nutritional support.

(D) staff needs and training.

(E) inpatient and outpatient medical coverage.

(F) transfusion and blood bank policies.

(G) transplant treatment protocols.

(H) hematopoiesis laboratory services and personnel.

(I) data management.

(J) quality assurance program.

(iv) Specify a schedule of site visits by staff of the existing BMT service that, at a minimum, includes:

(A) 3 visits during the first 12-months of operation of the proposed service.

(B) 3 visits during each the second 12-months and third 12-months of operation of the proposed service.

(v) Specify that the purpose of the site visits required by subdivision (iv) is to assess the proposed service and make recommendations related to quality assurance mechanisms of the proposed service, including at least each of the following:

(A) a review of the number of patients transplanted.

(B) transplant outcomes.

(C) all infections requiring treatment or life-threatening toxicity, defined for purposes of this agreement as National Cancer Institutes grade #3 or greater toxicity, excluding hematological toxicity.

(D) all deaths occurring within 100 days from transplant.
(E) each of the requirements of subdivision (iii).
(vi) Specify that a written report and minutes of each site visit shall be completed by the existing BMT service and sent to the proposed service within 2 weeks of each visit, and that copies of the reports and minutes shall be available to the Department upon request. At a minimum, the written report shall address each of the items in subdivision (v).
(vii) Specify that the existing BMT service shall notify the Department and the proposed service immediately if it determines that the proposed service may not be in compliance with any applicable quality assurance requirements, and develop jointly with the proposed service a plan for immediate remedial actions.
(viii) Specify that the existing BMT service shall notify the Department immediately if the consulting agreement required pursuant to these standards is terminated and that the notification shall include a statement describing the reasons for the termination.
(b) For purposes of subsection (10), "existing BMT service" means a service that meets all of the following:
(i) currently is performing and is FACT accredited in, the types of transplants (allogeneic and autologous; adult or pediatric) proposed to be performed by the applicant;
(ii) currently is certified as a National Marrow Donor Program; and
(iii) is located in the United States.
(c) An applicant shall document that the existing BMT service meets the requirements of subsection (b).

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

Sec 4. Acquisition of a BMT service means the acquisition (including purchase, lease, donation, or other arrangement) of an existing BMT service. An applicant proposing to acquire an existing BMT service shall demonstrate the following, as applicable to the proposed project.

(1) The applicant meets all of the requirements of this subsection and shall not be required to be in compliance with Section 3(5) and the department inventory.
(a) The total number of BMT services is not increased in the planning area as the result of the acquisition.
(b) As part of the acquisition of the BMT service, the acquisition or replacement of the cancer hospital, or for any other reasons, the location of the BMT service shall be located at its prior location or in space within the licensed cancer hospital site.
(c) The applicant is a cancer hospital as defined by these standards. ~~The applicant shall, to the satisfaction of the Department, provide verification of PPS-exemption at the time of application, or shall demonstrate compliance with the following to the satisfaction of the Department:~~
~~(i) The applicant, or an affiliate of the applicant, operates a comprehensive cancer center recognized by the National Cancer Institute in conjunction with a Michigan university that is designated as a comprehensive cancer center, or the applicant is the Michigan university that is designated as a comprehensive cancer center.~~
~~(ii) The applicant commits to provide evidence, satisfactory to the Department, of approval as a PPS-exempt hospital within the time limits specified in subsection (g).~~
(d) The applicant demonstrates that it meets, directly or through arrangements with the hospital from which it acquires the BMT service, the requirements set forth under Section 3(3), (6), (7), and (8), as applicable.
(e) The applicant agrees to either have a written consulting agreement as required by Section 3(10) or obtain a determination by the Department that such an agreement is not required because the existing BMT staff, services, and program substantially will continue to be in place after the acquisition.
(f) The applicant agrees and assures to comply, either directly or through arrangements with the hospital from which it acquires the BMT service, with all applicable project delivery requirements.

~~(g) If the applicant described in this subsection, or an applicant previously approved under this subsection, does not meet the Title XVIII requirements of the Social Security Act for exemption from PPS within 24 months after receiving CON approval under this section or such later date as the Department may have previously approved, the Department may extend the 24-month deadline to no later than the last session day permitted by the United States Constitution for the 113th United States Congress. Extension of the deadline until the end of the 113th Congress shall require the filing of a CON application under this section that provides demonstration by the applicant, to the satisfaction of the Department, that the applicant is continuing to pursue the PPS exemption. If the applicant fails to meet the Title XVIII requirements for PPS exemption within the 24-month period, or its possible extensions, then the Department may expire the CON granted pursuant to this subsection. However, prior to the Department expiring the CON, the original holder of the CON to provide the BMT service may apply for acquisition of the service, pursuant to all the provisions of this section, except for subsections (c) and (g).~~

(2) AN APPLICANT APPROVED FOR AND HOLDING A CON FOR BMT SERVICES UNDER THIS SECTION PRIOR TO THE EFFECTIVE DATE OF THIS REVISION OF THE BMT STANDARDS, (*INSERT EFFECTIVE DATE OF STANDARD),* SHALL APPLY TO REACQUIRE THE BMT SERVICE, AND THE ACQUIRED BMT SERVICE SHALL BE ACCOUNTABLE UNDER THESE REVISED STANDARDS.

(3) Applicants proposing to acquire an existing BMT service under this section shall not be subject to comparative review.

Section 5. Review standards for comparative reviews

Sec. 5. (1) Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and reviewed comparatively with other applications in accordance with the CON rules applicable.

(2) Each application in a comparative group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code being Section 333.22225 of the Michigan Compiled Laws and all other applicable requirements for approval in the Code and these standards. If the Department determines that two or more competing applications satisfy all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section 22225(1) being Section 333. 22225(1) of the Michigan Compiled Laws, and which have the highest number of points when the results of subsection (2) are totaled. If two or more qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1) of the Code, being Section 333. 22225(1) of the Michigan Compiled Laws, in the order in which the applications were received by the Department, based on the date and time stamp placed on the applications by the CON administrative unit of the Department responsible for administering the CON program when an application is submitted.

(3)(a) A qualifying project will have points awarded based on the straight-line distance to the nearest existing BMT service of the type applied for (adult or pediatric), as shown in the following schedule:

Straight-line Distance to Nearest BMT Service	Points Awarded
<75 miles	0
75 – 150 miles	1
>150 miles	2

(b) A qualifying project will have up to 4 points awarded based on the percentage of the medical/surgical indigent volume at the licensed site at which the proposed BMT service will be provided in accordance with the following:

(i) For each applicant in the same comparative group, determine the medical/surgical indigent volume. Determine the licensed site that has the highest indigent volume in the same comparative group. Divide the medical/surgical indigent volume for that licensed site by 4.0. The result is the indigent volume factor rounded to the nearest whole number.

(ii) For each applicant in the same comparative group, divide the medical/surgical indigent volume by the indigent volume factor determined in subdivision (i). The result, to the nearest whole number, is the number of points that will be awarded to each applicant pursuant to this subsection.

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total hospital charges expressed as a percentage, rounded to the nearest whole number, as determined by the Michigan Department of Community Health Medical Services Administration. The indigent volume data being used in this subsection is the data in the most current DCH-MSA Disproportionate Share Hospital (DSH) Report at the time the application(s) is deemed submitted by the Department.

(c) A qualifying project will have 2 points awarded if an applicant documents that, during the 36-month period prior to the date an application is submitted to the Department, at least 15 patients received pre- and post-transplant care at the licensed hospital site at which the BMT procedures will be performed and were referred for and received a BMT at an existing BMT service, and submits documentation from the existing BMT service(s) of these referrals.

(d) A qualifying project will have points awarded based on the number of necessary support services/personnel as identified in Section 7 that the applicant has available on-site on the date the application is submitted to the Department, as follows:

(i) 24-hour blood bank support, including pheresis capability, irradiated blood, products suitable for cytomegalovirus-negative transplants, and blood component therapy.

(ii) a processing and cryopreservation laboratory that meets the standards of the fact or an equivalent organization.

(iii) anatomic and clinical pathology with competency in interpreting pathologic findings related to graft-v-host disease and other opportunistic infections in immuno-compromised hosts.

(iv) therapeutic drug monitoring.

(v) one or more attending physicians with fellowship training, and/or at least 2 years of experience, in pediatric and/or adult BMT, as appropriate.

(vi) board-certified or board-eligible consulting physicians in all of the following areas: anatomic pathology with competence in graft versus host disease and other opportunistic diseases, infectious diseases with experience in immuno-compromised hosts, and radiation oncology with experience in total body irradiation.

(vii) a transplant team coordinator, with experience in evaluating pre and post BMT patients.

(viii) nurses with specialized training in pediatric and/or adult, as appropriate, BMT, hematology/oncology patient care, administration of cytotoxic therapies, management of infectious complications associated with host-defense mechanisms, administration of blood components, the hemodynamic support of the transplant patient, and managing immuno-suppressed patients.

(ix) a pharmacist experienced with the use of cytotoxic therapies, use of blood components, the hemodynamic support of the transplant patient, and the management of immuno-suppressed patients.

(x) an active, formal multi-disciplinary research program related to BMT.

(xi) a protective environmental inpatient unit for immuno-suppressed patients that has an isolation policy, an infection control plan specific to that unit, and air handling system capable of preventing nosocomial infections disseminated from central heating and cooling systems and ambient air.

The applicant shall receive points, up to a maximum of three (3), for this criterion according to the following schedule:

Number of BMT Support Personnel/Services Available	Points
zero or one	0
two to five	1
six to nine	2
ten or eleven	3

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

Section 6. Requirements for Medicaid participation

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

Section 7. Project delivery requirements terms of approval for all applicants

Sec. 7. An applicant shall agree that, if approved, the BMT service shall be delivered in compliance with the following terms of approval:

(1) Compliance with these standards. An applicant shall immediately report to the Department any changes in key staff or other aspects of the BMT service that may affect its ability to comply with these standards.

(2) Compliance with the following quality assurance requirements, as applicable, no later than the date the first BMT procedure, allogeneic or autologous, is performed:

(a) An applicant shall establish and maintain, either on-site or through written agreements, all of the following:

(i) 24-hour blood bank support, including pheresis capability, irradiated blood, products suitable for cytomegalovirus-negative transplants, and blood component therapy.

(ii) a cytogenetics and/or molecular genetic laboratory.

(iii) a processing and cryopreservation laboratory that meets the standards of the FACT or an equivalent organization.

(iv) a histocompatibility laboratory that has the capability of DNA-based HLA-typing and meets the standards of the American Society for Histocompatibility and Immunogenetics or an equivalent organization.

(v) anatomic and clinical pathology with competency in interpreting pathologic findings related to graft-v-host disease (programs performing allogeneic transplants) and other opportunistic infections in immuno-compromised hosts (programs performing allogeneic and autologous transplants).

(vi) therapeutic drug monitoring.

(b) An applicant shall establish and maintain, at the licensed hospital site at which the transplants are performed, both of the following:

(i) a protective environmental BMT inpatient unit for immuno-suppressed patients that has an isolation policy, an infection control plan specific to that unit, and an air handling system capable of preventing nosocomial infections disseminated from central heating and cooling systems and ambient air.

(ii) a specialized intensive care unit capable of treating immuno-suppressed neutropenic patients.

(c) An applicant shall establish and maintain written policies related to outpatient care for BMT patients, including at least the following:

(i) the ability to evaluate and provide treatment on a 24-hour basis.

(ii) nurses experienced in the care of BMT patients.

(iii) a designated outpatient area for patients requiring long-duration infusions or the administration of multiple medications or blood product transfusions.

(d) A BMT service shall establish and maintain a dedicated transplant team that includes at least the following staff:

(i) a transplant team leader, who is a physician that is board-certified in at least one of the following specialties: hematology, medical oncology, immunology, or pediatric hematology/oncology, as appropriate, and has had either at least one year of specific clinical training or two years of experience, both inpatient and outpatient, as an attending physician principally responsible for the clinical management of patients treated with hematopoietic transplantation. The team leader's experience shall include the clinical management of patients receiving an allogeneic transplant. The responsibilities of the transplant team leader shall include overseeing the medical care provided by attending physicians, reporting required data to the Department, and responsibility for ensuring compliance with the all applicable project delivery requirements.

(ii) one or more attending physicians with specialized training in pediatric and/or adult BMT, as appropriate. At least one attending physician shall have specialized training in allogeneic transplantation, adult or pediatric, as appropriate. An attending physician shall be board-certified or board-eligible in hematology, medical oncology, immunology, or pediatric hematology/oncology, as appropriate.

(iii) on-site availability of board-certified or board-eligible consulting physicians, adult and/or pediatric, as appropriate, in at least the following specialities: cardiology, gastroenterology nephrology, psychiatry, pulmonary medicine, and critical care medicine.

(iv) on-site availability of board-certified or board-eligible consulting physicians in the following areas: anatomic pathology with competence in graft versus host disease (services performing allogeneic transplants) and other opportunistic diseases (services performing allogeneic and autologous transplants), infectious diseases with experience in immuno-compromised hosts, and radiation oncology with experience in total body irradiation.

(v) a transplant team coordinator, who shall be responsible for providing pre-transplant patient evaluation and coordinating treatment and post-transplant follow-up and care.

(vi) a nurse to patient ratio necessary to provide care consistent with the severity of a patient's clinical status.

(vii) nurses with specialized training in pediatric and/or adult, as appropriate, BMT, hematology/oncology patient care, administration of cytotoxic therapies, management of infectious complications associated with compromised host-defense mechanisms, administration of blood components, the hemodynamic support of the transplant patient, and managing immuno-suppressed patients.

(viii) a pharmacist experienced with the use of cytotoxic therapies, use of blood components, the hemodynamic support of the transplant patient, and the management of immuno-suppressed patients.

(ix) dietary staff capable of providing dietary consultations regarding a patient's nutritional status, including total parenteral nutrition.

(x) designated social services staff.

(xi) designated physical therapy staff.

(xii) data management personnel designated to the BMT service.

(xiii) for an applicant performing pediatric BMT, a child-life specialist.

(e) In addition to the dedicated transplant team required in subsection (d), an applicant's staff shall include a patient ombudsman, who is familiar with the BMT service, but who is not a member of the transplant team.

(f) An applicant shall develop and maintain patient management plans and protocols that include the following:

(i) therapeutic and evaluative procedures for the acute and long-term management of a patient.

(ii) patient management and evaluation during the waiting, in-hospital and immediate post-discharge phases of the service.

(iii) long-term management and evaluation, including education of the patient, liaison with the patient's attending physician, and the maintenance of active patient records for at least 5 years.

(iv) IRB approval of all clinical research protocols, or if transplantation does not require an IRB-approved clinical research protocol, written policies and procedures that include at least the following: donor, if applicable, and recipient selection, transplantation evaluations, administration of the preparative regimen, post-transplantation care, prevention and treatment of graft-versus-host disease, and follow-up care.

(g) An applicant shall establish and maintain a written quality assurance plan.

(h) An applicant shall implement a program of education and training for nurses, technicians, service personnel, and other hospital staff.

(i) An applicant shall participate actively in the education of the general public and the medical community with regard to BMT, and make donation literature available in public areas of the institution.

(j) An applicant shall establish and maintain an active, formal multi-disciplinary research program related to the proposed BMT service.

(k) An applicant shall operate, either on-site or under its direct control, a multi-disciplinary selection committee which includes, but is not limited to, a social worker, a mental health professional, and physicians experienced in treating BMT patients.

(l) A pediatric BMT service shall maintain membership status in the Children's Oncology Group (COG).

(m) For purposes of evaluating subsection (2), except subdivision (k), the Department shall consider it prima facie evidence as to compliance with the applicable requirements if an applicant documents that the BMT service is accredited by the National Marrow Donor Program (NMDP) or the Foundation for the Accreditation of Cell Therapy (FACT).

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

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

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

(c) The BMT service shall not deny BMT services to any individual based on ability to pay or source of payment.

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

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

(a) An adult BMT service shall perform at least 30 transplants, of which at least 10 are allogeneic transplants, in the third 12-months of operation and annually thereafter.

(b) A pediatric BMT service shall perform at least 10 transplants, of which at least 5 are allogeneic transplants, in the third 12-months of operation. After the third 12-months of operation, an applicant shall perform at least 30 pediatric transplants in any 36-month consecutive period, with no fewer than 5 allogeneic transplants in any 12-month period, beginning with the third 12-months of operation, and thereafter.

(c) A BMT service that performs both adult and pediatric BMT shall specify whether each patient age 18-20 is included in the category of adult procedures or the category of pediatric procedures. An applicant shall determine for each patient age 18-20 whether to record that patient as an adult or a pediatric procedure, but an applicant shall record each patient age 18-20 in only 1 category.

(d) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, demographic and diagnostic information, primary and secondary diagnoses, whether the transplant procedure was a first or repeat transplant procedure, length of stay, the volume of care provided to patients from all payor sources, and other data requested by the Department and approved by the CON Commission. The applicant shall provide the required data on an individual basis for each designated licensed site; in a format established by the Department; and in a mutually-agreed upon media. The Department may elect to

verify the data through on-site review of appropriate records. In addition, an applicant shall report at least the following data for each patient:

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

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

(e) The applicant shall maintain an organized institutional transplant registry for recording ongoing information on its patients being evaluated for transplant and on its transplant recipients and shall participate in the national and international registries applicable to the BMT service.

(f) The BMT service shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules. A BMT service that initially does not perform both allogeneic and autologous procedures also shall notify the Department when it begins to perform autologous procedures.

(g) An applicant shall notify the Department immediately if the consulting agreement required pursuant to Section 3(10) of these standards is terminated prior to the end of the first 36-months of operation of the BMT service. The notification shall include a statement describing the reasons for the termination. An applicant shall have 30 days following termination of that agreement to enter into a written consulting agreement that meets the requirements of Section 3(10). An applicant shall provide the Department with a copy of that written consulting agreement.

(h) The Department may use the information provided pursuant to Section 3(10) of these standards in evaluating compliance with the requirements of this section.

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

Section 8. Documentation of projections

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

Section 9. Department Inventory of BMT Services

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

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

Sec. 10. (1) These CON review standards supersede and replace the CON Review Standards for Extrarenal Organ Transplantation Services pertaining to BMT services approved by the CON Commission on ~~September 23~~DECEMBER 13, ~~2010~~ 2012 and effective on ~~December~~ MARCH ~~3~~22, ~~2010~~2013.

(2) Projects reviewed under these standards shall be subject to comparative review except for Section 4.

APPENDIX A

Counties assigned to each health service area 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

FINAL REPORT AND RECOMMENDATIONS
Nursing Home-Hospital Long Term Care Unit CON Standards

To: **CON Commission**
From: **Karen J. Messick, MPA, LNHA**
CON Workgroup Chair
Date: **June 12, 2014 CON Commission meeting**
RE: **CON Workgroup report and recommendations**

The CON Workgroup met six times: December 18, 2013, January 16, 2014, February 13, 2014, March 27, 2014, April 8, 2014, and May 14, 2014

The workgroup was tasked with five charges (please see attachment 1). Charge 1 was to consider modifications to the comparative review criteria. By group decision, the majority of our time was focused on Charge 1. A sub-group was formed to work on recommendations with regard to Section 10(2) and 10(3) of the comparative review criteria regarding Medicare and Medicaid certification in relationship to the points awarded. The sub-group made their recommendation at the March 27th workgroup meeting, the recommendation was vetted and the final decision is included in our overall recommendations.

Another sub-group was formed to review Section 10(5) of the comparative review criteria regarding culture change with the objective to recommend any criteria changes. That group presented to the full workgroup on March 27th, the recommendations were vetted and are included in our overall recommendations.

The Department has been very helpful during this process (i.e. Beth, Brenda, Natalie, Tulika, and Joette). Spreadsheets were created to show all the comparative review criteria, scoring, etc. Other supporting information was also provided by the department to help us in our discussions. We used the spreadsheets to work through Section 10 of the comparative review in developing our final recommendations. In addition, Mr. Perry Smith, MDCH/CON, and Mr. Jim Scott, Licensing and Regulatory Affairs-BHS Engineer, attended specific workgroup meetings upon request to clarify requirements as we worked through the charges.

The intention for spending the amount of time we did on Charge 1 was to ensure we were making recommendations that not only made sense now but also in the future as health care reform begins to make its mark on skilled beds. Further, by resolving the criteria issues of Charge 1, we were able to work more effectively through the other charges as most of those discussions were also a part of the Charge 1 work.

At the February 13, 2014 CON Workgroup meeting, The Hospice and Palliative Care Association of Michigan presented a letter and recommendation to the Chair and the workgroup asking that Charge 4: "addition of 130 beds to the special pool for hospice" be removed from our charge list (please see attachment 2). The workgroup agreed unanimously with the recommendation to remove Charge 4.

Attachment 3 is a spreadsheet summary of the changes discussed in this report related to Section 10.

Finally and before proceeding with the workgroup recommendations to the CON Commission, I would like to acknowledge and thank the workgroup participants and the department for their outstanding work over these past five months. Ground rules for workgroup participation were established at the first meeting and revisited at the beginning of each subsequent meeting. The ground rules also helped establish a focus on only the charges at hand (recommendations not related to the original five charges are included in attachment 4).

The workgroup respected and adhered to the ground rules and, for this, I am most grateful. As this was my first role as chair of a CON workgroup with no prior experience with which to compare, I submit that we were thoughtful, diligent, respectful, and productive in accomplishing our task. The workgroup included an excellent representation of advocacy and professional diversity from all over Michigan: attorneys, the Ombudsman's office, staff from various state departments representing policy and rules, providers, insurers, hospice, health care and hospital associations, and Medicaid just to mention a few (note: this list is not all inclusive).

CON Workgroup recommendations and rationale: In all recommendations, please refer to the draft of the CON Standards. **Note:** recommendations to point value changes have been made to the standards. However, at no place do these recommendations exceed the primary point values of the Medicare and Medicaid percentage requirements for patient days and bed certification.

Charge 1: Modifications to the comparative review criteria
Section 10:

10(2)(a)(i) and 10(2)(a)(ii): Qualifying project points for percentage of Medicaid patients days of care.

- After sub-group deliberation and considerable discussion by the full workgroup, it was determined that CON legislation requires this percentage in CON points awards. The points and percentages were changed to reflect the workgroup's desire to raise the bar for existing and proposed projects since one of the main goals of CON is to ensure access under Medicaid.

10(2)(b): Qualifying project awarded points for some determined percentage of Medicaid beds.

- Workgroup eliminated 10(2)(b)(i) and (ii) and created 10(2)(b) to specifically read: "If all beds in the proposed project will be dually certified for both Medicare and Medicaid services by the second 12 months of operation" then 10 points will be awarded.

  The rationale for this change was based on the redundant, unnecessary complexity of the old requirements, to ensure enhanced Medicaid access for those requiring the need for care. By recognizing the second 12 month period of operation would include existing and new qualifying projects starting when the CON is awarded.

Old 10(3): Participation in the Medicare program for the most recent 12 months.

- Delete; deemed unnecessary in relationship to the recommendations for 10(2)(a) and (b) above

10(3)(a) New number: Currently identified as a special focus NH-HLTCU by CMS.

- Delete; redundant to the remaining sections of 10(4)

10(4): Participation in a cultural change model.

- Workgroup asked MDCH to remove the Wellspring model from the review criteria as it no longer exists. Additionally, it was determined to award points accordingly: 3 points for a qualifying project if the applicant provides documentation to participate or proposes to participate in a culture change model. An additional 5 points will be awarded if the model is one approved by the department.

  The rationale for this recommendation is two-fold: first, to recognize that culture change comes in many packages-off the shelf and self designs. Some organizations have developed very good culture change programs but are not on the MDCH/CON approved list. The additional 5 points are awarded to those providers who have chosen a department-approved culture change model.

10(5): Applicant cash.

- The workgroup added language to the definition of applicant cash [Section 2(1)(c)] to include contributions from lease holders; deleted old 10(11) which awarded 5 points for providing audited statements

  The rationale for this recommendation appropriately includes the investment by the lease holder.

Old 10(6) Deleted: A qualifying project will be awarded 5 points if the existing or proposed NH-HLTCU is fully equipped with sprinklers.

- Deleted; the workgroup verified with the State Fire Marshall that sprinkling is now Federal law as of 8/2013 and confirmed that the State of Michigan complies.

10(6): Qualifying project will be equipped with air conditioning

- The workgroup amended the language to read: "A qualifying project will be awarded 4 points if the ENTIRE existing and proposed NH-HLTCU is fully equipped with air conditioning AS DEFINED IN THE 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."

  The rationale for this recommendation is to ensure improved climate control for the entire facility.

(Facility Design criteria):

10(7): 100% rooms with adjoining sink, toilet, and shower.

- The workgroup amended the language to read: "A qualifying project will be awarded SIX (6) OR FOUR (4) points based on the proposed project as follows:
  - 100% rooms with DEDICATED TOILET ROOM CONTAINING A SINK, WATER CLOSET, AND SHOWER (6 POINTS)
  - 80% private rooms with dedicated TOILET ROOM CONTAINING A SINK, WATER CLOSET, AND SHOWER (4 POINTS)

  The rationale for this change to the prior language is to incent qualifying projects to create or update space to be more homelike and less institutional. The workgroup indicated that private citizens do not have sinks in their living areas and do not believe NH-HLTCU patients should

either. There is a need for semi private rooms to accommodate couples and other lifestyles hence the second bullet point and subsequent point award.

10(8): A qualifying project will be awarded 10 points if it results in an NH-HLTCU with 150 or fewer beds.

- "IN TOTAL" was added to the end of the statement in 10(10)

The rationale for this recommendation is not to create large campuses which could include both skilled nursing and assisted living.

Old 10(11) Deleted: Audited financial statements.

- Deleted and added to 10(5) "Applicant Cash"

The workgroup determined section 10(11) was redundant because it is already addressed in the Administrative Rules.

10(10): Elimination of existing 3/4 bed wards.

- The workgroup amended the language to read: "…will have no more than double occupancy at the completion of the project."

The rationale simply is the belief that wards are not appropriate for good care

10(11): The qualifying project is on a readily accessible public transportation route.

- Points were changed from 5 to 2

The rationale was to balance the points of comparative review based on better relevance to the care of residents.

(Technology criteria changed to "Innovations")

10(12):

The workgroup recommended the following changes to the Innovation criteria:

- THE PROPOSED PROJECT WILL HAVE WIRELESS NURSE CALL/PAGING SYSTEM INCLUDING WIRELESS DEVICES CARRIED BY DIRECT CARE STAFF.

- WIRELESS INTERNET WITH RESIDENT ACCESS TO RELATED EQUIPMENT/DEVICE IN ENTIRE FACILITY.

- 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.

- THE PROPOSED PROJECT WILL HAVE A BACKUP GENERATOR SUPPORTING ALL FUNCTIONS WITH AN ON-SITE FUEL SUPPLY AND BE CAPABLE OF PROVIDING AT LEAST 48 HOURS OF SERVICE AT FULL LOAD.

The rationale for the workgroup recommendations after sub-group presentation was to recognize technology changes in these areas and look towards what will be changing in the immediate future.

Additionally, the workgroup added language related to an enhanced generator support to recognize recent outage issues.

10(13): New criteria for Bariatric rooms

- THE PROPOSED PROJECT INCLUDES BARIATRIC ROOMS AS FOLLOWS: PROJECT USING 0 – 49 BEDS WILL RESULT IN AT LEAST 1 BARIATRIC ROOM OR PROJECT USING 50 OR MORE BEDS WILL RESULT IN AT LEAST 2 BARIATRIC ROOMS [BARIATRIC ROOM MEANS THE CREATION OF PATIENT ROOM(S) INCLUDED AS PART OF THE CON PROJECT, AND IDENTIFIED ON THE ARCHITECTURAL SCHEMATICS, THAT ARE DESIGNED TO ACCOMMODATE THE NEEDS OF BARIATRIC PATIENTS WEIGHING OVER 400 POUNDS. THE BARIATRIC PATIENT ROOMS SHALL HAVE A LARGER ROOM AND BATHROOM ENTRANCE WIDTH TO ACCOMMODATE OVER-SIZED EQUIPMENT, AND SHALL INCLUDE A MINIMUM OF A BARIATRIC BED, BARIATRIC TOILET, BARIATRIC WHEELCHAIR, AND A DEVICE TO ASSIST RESIDENT MOVEMENT (SUCH AS A PORTABLE OR BUILD IN LIFT). IF AN IN-ROOM SHOWER IS NOT INCLUDED IN THE BARIATRIC PATIENT ROOM, THE MAIN/CENTRAL SHOWER ROOM THAT IS LOCATED ON THE SAME FLOOR AS THE BARIATRIC PATIENT ROOM(S) SHALL INCLUDE AT LEAST ONE SHOWER STALL THAT HAS AN OPENING WIDTH AND DEPTH THAT IS LARGER THAN MINIMUM MI CODE REQUIREMENTS.

  The rationale for this recommendation is to ensure access to care for bariatric individuals.

Charge 2: Elimination of the restrictive relocation criteria

- Section 7 was moved to Section 8 and the recommended changes are as follows:
  - Elimination of the 50% of the beds to another NH-HLTCU to make it consistent between the two types of units
  - Elimination of the 7 year relocation restriction
  - Added the relocated beds cannot create three or more bed wards

  The rationale for these recommendations was to better accommodate access to care.

Charge 3: Elimination of the 3 mile radius replacement requirement-Replacement beds, Sect. 7(3)(c)(i)

- The workgroup changed the language to read: "The proposed site for the replacement beds is in the same planning area." The 3 mile radius language was removed because it was initially put in because of new model design which is no longer relevant.

Charge 4: Addition of 130 beds to the special pool for Hospice

- The Hospice and Palliative Care Association of Michigan requested that this charge be removed. See attachment 2.

Charge 5: Technical changes

- The department corrected for consistency within CON standards and changes within the department structures (i.e. BHS to LARA) as well as grammatical changes. These enhancements include an addition to Section 11 indicating accountability of the applicant to complying with the CON award criteria for the approved project.

Workgroup concerns outside of the 5 charges:

1. The recognition that skilled nursing services are going to a more post acute care environment where patients are of higher care and recognizing that level of care through the CON process. We were not able to come to consensus on this issue and the issue will continue to grow in terms of access to care.
2. The current CON process requires the applicant to be site/location specific. However, due to the time required to approve a CON application, the location may no longer be appropriate or available. The workgroup discussed this concern at length and the department stated that this could not be addressed through the standards. We recommend that this be further reviewed and addressed by the appropriate mechanism be it legislative or administrative rules.
3. The CON planning areas for these standards are based on geographic county region with the exception of Wayne County which has 3 geographic regions. Whether geographic regions is appropriate at this time given the shift in the state's population is a matter of concern for the workgroup and we respectfully recommend this issue be further reviewed. . Please also see the letter submitted as attachment 4 from LeadingAge of Michigan.

Lastly, the workgroup identified a serious technical error which the group was unable to correct. It concerns the availability of data from LARA that is used by CON numerous times to make application determinations based on survey citations at a Level D or above. Please see Section 6, 1(a)(iv) of the CON standards which is the first mention of many in the standards. This needs to be corrected in order to properly implement the CON standards. The workgroup strongly recommends that the data has to be current and correct or the standard must be changed.

Attachment D

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CON Commission Testimony
Nursing Home and Hospital LTC Unit Standards

Good morning! I am Pat Anderson Executive Vice President of Reimbursement Services for the Health Care Association of Michigan. Thank you for the opportunity to testify on behalf of HCAM in support of the CON Workgroup recommendations for the nursing home and HLTCU standards HCAM is a statewide trade association representing 300 nursing facilities, county medical care facilities and hospital long term care units across Michigan.

I had the privilege to serve on this workgroup with colleagues who worked in a very cooperative, lively and collaborative nature. Our chair Karen Messick was outstanding in keeping all of us focused on the charge from the Commission and fostering our discussions as we came to consensus on the recommendations. As I stated HCAM supports all of the recommendations from the workgroup as incorporated in the revised standards.

On behalf of HCAM I would like to highlight two areas that were discussed but not resolved by the workgroup. The first area is the change in the level of care provided by these healthcare providers referred to as post-acute care. These providers have made continuous strides in providing more Medicare post acute services from an average of less than 10% to over 20% of the days of care. This dynamic was discussed at the workgroup level but no appropriate change could be made to accommodate this change or these types of providers; especially those providers who focus on post acute care and desire to have beds with only Medicare certification. This post acute care will continue to grow and should be a concern to address in future reviews of the standards.

HCAM's other concern is regarding the CON requirement of site specific location at time of obtaining the CON. As described in the workgroup report the availability of this site for this purpose is either not appropriate or unavailable by the time the CON is issued. HCAM will be pursuing further discussion on this issue with the department and/or legislature as needed to allow for exceptions to the site specific requirement.

The last item HCAM would like to express concern with is the report's recommendation to obtain the correct and updated citation data from the Department of Licensing and Regulatory Affairs (LARA). Incorrect data seems to provide the ripe environment to encourage an appeal on a decision if the applicant is impacted by this data as used in the standard.

Thank you for this opportunity to testify.

CON Commission Testimony
Of David G. Stobb
Nursing Home and Hospital LTC Unit Standards
June 12, 2014

My name is David Stobb and I am General Counsel of Ciena Healthcare. My company is based in Southfield and we manage over 30 skilled nursing facilities in Michigan. I am here to testify in support of the recommendations being made by the CON Workgroup for changes to be made to the Nursing Home and HLTCU standards.

I was a participant in the Workgroup meetings. The Workgroup represented a wide variety of interests. Our discussions were detailed, meaningful and productive with a sustained focus on raising the bar on future skilled nursing development in terms of quality, safety, resident-centered care and encouraging cutting edge delivery of care to our residents. With the outstanding leadership of the Workgroup Chair, Karen Messick, I am proud to say the Workgroup recommendations will indeed raise the bar on the future of long term care and short term rehabilitation services for Michigan residents.

I do want to bring to the attention of the Commission one item that the Workgroup was not able to include in its recommendations relating to changes needed in the Standards that would allow the Department to have discretion to allow an approved project that has not been constructed to change the project site due to building and development hardships experienced by the applicant at the originally identified CON site.

The Workgroups Final Report and Recommendations to the CON Commission as follows:

> The current CON process requires the applicant to be site/location specific. However, due to the time required to approve a CON application, the location may no longer be appropriate or available. The workgroup discussed this concern at length and the department stated that this could not be addressed through the standards. We recommend that this be further reviewed and addressed by the appropriate mechanism be it legislative or administrative rules.

Ciena has constructed more new facilities in Michigan in the past 5 years than any other provider. It has been our experience that it is not always possible to construct an approved project at the exact site identified in the original CON application submitted for the project. Occasionally, the original site identified in a CON application can no longer be used due to circumstances beyond the applicant's control, and proceeding with the project at the original site will caused undue hardship to the applicant or be impossible altogether.

While the CON standards and rules provide the Department with wide discretion on awarding and enforcing Certificates of Need, the Department has taken the position that they have no discretion to allow a site change on an approved project, even where the applicant has experienced site specific hardships beyond their control such as zoning approval, environmental matters, site challenges.

Ciena introduced a proposal to the Workgroup that would allow an applicant to apply for a new Certificate of need to relocate an unbuilt approved project to a new site where the applicant can demonstrate hardship in developing the project at the original site. This proposal fits within the Standards that allow an existing licensed facility to relocate to a new site by obtaining a CON to relocate. This just makes common sense. However, the Department's response to this proposal was that the CON rules only permit a site change by way of amendment to the CON and the rules for an amendment prohibit the change of a site.

I respectfully disagree with this position. Ciena's relocation proposal is consistent with the recently-amended CON Rules, which provides in Rule 325.9105(g) that a "site" is "the physical location and address of a covered service or beds, unless otherwise defined in the applicable certificate of need review standards. The Standards thus can, by a change made though this Commission, define a "site" as a relocation of a yet to be built approved project. Unfortunately, the Department unnecessarily shut down this proposed change to the Standards instead of addressing the merits of the issue. As a result, some approved projects through the state will not be able to be built, resulting in loss of access to care for residents and loss of the opportunity to create much needed jobs in our state.

I would urge the Commission to consider and approve the proposal discussed in the Workgroup that would allow a change of site to an unbuilt project.

Thank you for this opportunity to testify

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

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

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval ~~and delivery of nursing homes and HLTCU services~~ under Part 222 of the Code THAT INVOLVE A) BEGINNING OPERATION OF A NEW NURSING HOME/HLTCU, (B) REPLACING BEDS IN A NURSING HOME/HLTCU OR PHYSICALLY RELOCATING NURSING HOME/HLTCU BEDS FROM ONE LICENSED SITE TO ANOTHER GEOGRAPHIC LOCATION, (C) INCREASING LICENSED BEDS IN A NURSING HOME/HLTCU ~~. A nursing home~~ licensed under Part 217 and a HLTCU defined in Section 20106(6), OR (D) ACQUIRING A NURSING HOME/HLTCU. PURSUANT TO THE CODE, A NURSING HOME/HLTCU ~~are~~ IS A covered health ~~facilities~~ facilitY ~~for purposes of Part 222 of the Code~~. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(2) AN INCREASE IN LICENSED NURSING HOME/HLTCU BEDS IS A CHANGE IN BED CAPACITY FOR PURPOSES OF PART 222 OF THE CODE.

(3) THE PHYSICAL RELOCATION OF NURSING HOME/HLTCU BEDS FROM A LICENSED SITE TO ANOTHER GEOGRAPHIC LOCATION IS A CHANGE IN BED CAPACITY FOR PURPOSES OF PART 222 OF THE CODE.

Section 2. Definitions

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

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

(b) "ADC adjustment factor" means the factor by which the average daily census (ADC), derived during the bed need methodology calculation set forth in Section 3(2)(d) for each planning area, is divided. For planning areas with an ADC of less than 100, the ADC adjustment factor is 0.90 and for planning areas with an ADC of 100 or more, the ADC adjustment factor is 0.95.

(c) "Applicant's cash" means the total unrestricted cash, designated funds, and restricted funds reported by the applicant as the source of funds in the application. IF THE PROJECT INCLUDES SPACE LEASE COSTS, THE APPLICANT'S CASH INCLUDES THE CONTRIBUTION DESIGNATED FOR THE PROJECT FROM THE LANDLORD.

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

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

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

(g) "Common ownership or control" means a nursing home, regardless of the state in which it is located, that is owned by, is under common control of, or has a common parent as the applicant nursing home pursuant to the definition of common ownership or control utilized by the Department~~'s~~ OF LICENSING AND REGULATORY AFFAIRS~~'s~~(LARA), Bureau of Health ~~Systems~~CARE SERVICES.

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

(i) "Converted space" means existing space in a health facility that is not currently licensed as part of the nursing home/HLTCU and is proposed to be licensed as nursing home or HLTCU space. An example is proposing to license home for the aged space as nursing home space.

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

(k) "Department inventory of beds" means the current list, for each planning area maintained on a continuing basis by the Department: (i) licensed nursing home beds and (ii) nursing home beds approved by a valid CON issued under Part 222 of the Code which are not yet licensed. It does not include (a) nursing home beds approved from the statewide pool and (b) short-term nursing care program beds approved pursuant to Section 22210 of the Code, being Section 333.22210 of the Michigan Compiled Laws.

(l) "Existing nursing home beds" means, for a specific planning area, the total of all nursing home beds located within the planning area including: (i) licensed nursing home beds, (ii) nursing home beds approved by a valid CON issued under Part 222 of the Code which are not yet licensed, (iii) proposed nursing home beds under appeal from a final Department decision made under Part 222 or pending a hearing from a proposed decision issued under Part 222 of the Code, and (iv) proposed nursing home beds that are part of a completed application under Part 222 of the Code which is pending final Department decision. (a) Nursing home beds approved from the statewide pool are excluded; and (b) short-term nursing care program beds approved pursuant to Section 22210 of the Code, being Section 333.22210 of the Michigan Compiled Laws, are excluded.

(m) "Health service area" or "HSA" means the geographic area established for a health systems agency pursuant to former Section 1511 of the Public Health Service Act and set forth in Section 14.

(n) "Hospital long-term-care unit" or "HLTCU" means a nursing care facility, owned and operated by and as part of a hospital, that provides organized nursing care and medical treatment to seven (7) or more unrelated individuals suffering or recovering from illness, injury, or infirmity.

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

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

(q) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396~~r-6~~ TO 1396G and1396~~r-8~~l to ~~1396v~~1396U.

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

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

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

(~~u~~s) "Nursing home" means a nursing care facility, including a county medical care facility, but excluding a hospital or a facility created by Act No. 152 of the Public Acts of 1885, as amended, being sections 36.1 to 36.12 of the Michigan Compiled Laws, that provides organized nursing care and medical

treatment to seven (7) or more unrelated individuals suffering or recovering from illness, injury, or infirmity. This term applies to the licensee only and not the real property owner if different than the licensee.

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

(~~w~~u) "Occupancy rate" means the percentage which expresses the ratio of the actual number of patient days of care provided divided by the total number of patient days. Total patient days is calculated by summing the number of licensed and/or CON approved but not yet licensed beds and multiplying these beds by the number of days that they were licensed and/or CON approved but not yet licensed. This shall include nursing home beds approved from the statewide pool. Occupancy rates shall be calculated using verifiable data from ~~either (i)~~ the actual number of patient days of care for 12 continuous months of data from the ~~MDCH~~ CON Annual Survey ~~of Long-Term-Care Facilities~~ or other comparable MDCH survey instrument ~~or (ii) the actual number of patient days of care for 4 continuous quarters of data as reported to the Department for purposes of compiling the "Staffing/Bed Utilization Ratios Report," whichever is the most recent available data~~.

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

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

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

(~~aa~~x) "Relocation of existing nursing home/HLTCU beds" means a change in the location of existing nursing home/HLTCU beds from the licensed site to a different EXISTING licensed site within the planning area.

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

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

(~~dd~~aa) "Replacement zone" means a proposed licensed site that is,

(i) for a rural or micropolitan statistical area county, within the same planning area as the existing licensed site.

(ii) for a county that is not a rural or micropolitan statistical area county,

(A) within the same planning area as the existing licensed site and

(B) within a three-mile radius of the existing licensed site.

~~(ee) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix C.~~

~~(ffcc) "Staffing/Bed Utilization Ratios Report" means the report issued by the Department on a quarterly basis.~~

(~~gg~~bb) "Use rate" means the number of nursing home and hospital long-term-care unit days of care per 1,000 population during a one-year period.

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

Section 3. Determination of needed nursing home bed supply

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

(b) The age cohorts for each planning area shall be: (i) age 0 - 64 years, (ii) age 65 - 74 years, (iii) age 75 - 84 years, and (iv) age 85 and older.

(c) Until the base year is changed by the Commission in accord with Section 4(3) and Section 5, the use rates for the base year for each corresponding age cohort, established in accord with subsection (1)(b), are set forth in Appendix ~~A~~B.

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

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

(b) Multiply each population age cohort by the corresponding use rate established in Appendix ~~A~~B.

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

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

(e) The following shall be known as the ADC adjustment factor. (i) If the ADC determined in subsection (d) is less than 100, divide the ADC by 0.90. (ii) If the ADC determined in subsection (d) is 100 or greater, divide the ADC by 0.95.

(f) The number determined in subsection (e) represents the number of nursing home beds needed in a planning area for the planning year.

Section 4. Bed need

Sec. 4. (1) The bed need numbers ~~shown in Appendix B and incorporated as part of these standards~~ shall apply to project applications subject to review under these standards, except where a specific CON standard states otherwise.

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

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

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

(5) New bed need numbers established by subsections (2) and (3) shall supersede ~~the~~ PREVIOUS bed need numbers ~~shown in Appendix B~~ and shall be ~~included as an amended appendix to these standards~~POSTED ON THE STATE OF MICHIGAN CON WEB SITE AS PART OF THE NURSING HOME/HLTCU BED INVENTORY.

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

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

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

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

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

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

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

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

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

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

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated

from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid services.

(vi) ~~Outstanding~~ DELINQUENT debt obligation to the State of Michigan ~~for~~ INCLUDING, BUT NOT LIMITED TO, Quality Assurance Assessment Program (QAAP), PREADMISSION SCREENING AND ANNUAL RESIDENT REVIEW (PASARR) ~~or~~ Civil Monetary Penalties (CMP).

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

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

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

(i) An applicant may request and be approved for up to a maximum of 20 beds if, when the total number of "existing nursing home beds" is subtracted from the bed need for the planning area ~~set forth in Appendix B~~, the difference is equal to or more than 1 and equal to or less than 20. This subsection is not applicable to projects seeking approval for beds from the statewide pool of beds.

(ii) An exception to the number of beds may be approved, if the applicant facility has experienced an average occupancy rate of 97% for ~~12 quarters~~THREE YEARS based on the ~~Department's "Staffing/Bed Utilization Ratios Report."~~CON ANNUAL SURVEY. The number of beds that may be approved in excess of the bed need for each planning area ~~identified in Appendix B~~ is set forth in subsection (A).

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

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

(A) The planning area in which the beds will be located shall have a population density of less than 28 individuals per square mile based on the ~~2000~~ 2010 U.S. Census figures as set forth in Appendix ~~D~~E.

(B) The applicant facility has experienced an average occupancy rate of 92% for the most recent ~~24 months~~TWO YEARS based on the ~~Department's "Staffing/Bed Utilization Ratios Report."~~CON ANNUAL SURVEY.

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

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

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

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) ~~Outstanding~~ DELINQUENT debt obligation to the State of Michigan INCLUDING, BUT NOT LIMITED TO, ~~for~~ Quality Assurance Assessment Program (QAAP), PREADMISSION SCREENING AND ANNUAL RESIDENT REVIEW (PASARR) or Civil Monetary Penalties (CMP).

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

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

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

(A) at least 100% of all resident sleeping rooms shall meet barrier free requirements;
(B) electronic nurse call systems shall be required in all facilities;
(C) handrails shall be required on both sides of patient corridors; and
(D) ceiling heights shall be a minimum of 7 feet 10 inches.
(iii) The proposed project shall comply with applicable life safety code requirements and shall be fully sprinkled and air conditioned.
(iv) The Department may waive construction requirements for new design model projects if authorized by law.
(c) The proposed project shall include at least 80% single occupancy resident rooms with an adjoining ~~bathroom~~TOILET ROOM CONTAINING A SINK, WATER CLOSET, AND BATHING FACILITY AND serving no more than two residents in both the central support inpatient facility and any supported small resident housing units.
(d) The proposed increase, if approved, will not result in the total number of existing nursing home beds in that planning area exceeding the needed nursing home bed supply ~~set forth in Appendix B~~, unless the following is met:
(i) An approved project involves replacement of a portion of the beds of an existing facility at a geographic location within the replacement zone that is not physically connected to the current licensed site. If a portion of the beds are replaced at a location that is not the current licensed site, a separate license shall be issued to the facility at the new location.
(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health ~~Systems~~ CARE SERVICES within ~~the Department~~LARA. Code deficiencies include any unresolved deficiencies still outstanding with ~~the Department~~LARA.

~~**Section 7. Requirements for approval to relocate existing nursing home/HLTCU beds**~~

~~Sec. 7. (1) An applicant proposing to relocate existing nursing home/HLTCU beds shall not be required to be in compliance with the needed nursing home bed supply set forth in Appendix B, if the applicant demonstrates all of the following:~~
~~(a) An existing nursing home may relocate no more than 50% of its beds to another existing nursing home, and an existing HLTCU may relocate all or a portion of its beds to another existing nursing home/HLTCU.~~
~~(b) The nursing home/HLTCU from which the beds are being relocated and the nursing home/HLTCU receiving the beds shall not require any ownership relationship.~~
~~(c) The nursing home/HLTCU from which the beds are being relocated and the nursing home/HLTCU receiving the beds must be located in the same planning area.~~
~~(d) The nursing home/HLTCU from which the beds are being relocated has not relocated any beds within the last seven (7) years.~~
~~(e) The relocated beds shall be licensed to the receiving nursing home/HLTCU and will be counted in the inventory for the applicable planning area.~~
~~(f) At the time of transfer to the receiving facility, patients in beds to be relocated must be given the choice of remaining in another bed in the nursing home/HLTCU from which the beds are being transferred or to the receiving nursing home/HLTCU. Patients shall not be involuntary discharged to create a vacant bed.~~

~~(2) An applicant proposing to add new nursing home/HLTCU beds, as the receiving existing nursing home/HLTCU under subsection (1), shall not be required to be in compliance with the needed nursing home bed supply set forth in Appendix B, if the applicant demonstrates all of the following:~~
~~(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:~~

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

~~(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.~~

~~(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.~~

~~(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.~~

~~(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.~~

~~(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.~~

~~(vi) Outstanding debt obligation to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP).~~

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

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

Section ~~8~~7. Requirements for approval to replace beds

Sec. ~~8~~7. An applicant proposing to replace beds must meet the following as applicable.

(1) An applicant proposing to replace beds within the replacement zone shall not be required to be in compliance with the needed nursing home bed supply ~~set forth in Appendix B~~ AND~~if the applicant demonstrates~~ all of the following REQUIREMENTS ARE MET:

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

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control

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

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) ~~Outstanding~~ DELINQUENT debt obligation to the State of Michigan INCLUDING, BUT NOT LIMITED TO, ~~for~~ Quality Assurance Assessment Program (QAAP), PREADMISSION SCREENING AND ANNUAL RESIDENT REVIEW (PASARR) or Civil Monetary Penalties (CMP).

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

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

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

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

(2) An applicant proposing to replace a licensed nursing home/HLTCU outside the replacement zone shall demonstrate all of the following:

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

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

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

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) ~~Outstanding~~ DELINQUENT debt obligation to the State of Michigan INCLUDING, BUT NOT LIMITED TO, ~~for~~ Quality Assurance Assessment Program (QAAP), PREADMISSION SCREENING AND ANNUAL RESIDENT REVIEW (PASARR) or Civil Monetary Penalties (CMP).

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

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

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

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

(3) An applicant proposing to replace beds with a new design model shall not be required to be in compliance with the needed nursing home bed supply ~~set forth in Appendix B~~ AND~~if the applicant demonstrates~~ all of the following REQUIREMENTS ARE MET:

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

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

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

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

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

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

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

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

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

(b) The proposed project shall include at least 80% single occupancy resident rooms with an adjoining ~~bathroom~~TOILET ROOM CONTAINING A SINK, WATER CLOSET, AND BATHING FACILITY AND serving no more than two residents in both the central support inpatient facility and any supported small resident housing units. If the proposed project is for replacement/renovation of an existing facility and utilizes only a portion of its currently licensed beds, the remaining rooms at the existing facility shall not exceed double occupancy.

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

(i) The proposed site for the replacement beds is in the same planning area~~, and not within a three mile radius of a licensed nursing home that has been newly constructed, or replaced (including approved projects) within five calendar years prior to the date of the application~~,

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

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

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

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

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

Sec. 8. (1) An applicant proposing to relocate existing nursing home/HLTCU beds shall not be required to be in compliance with the needed nursing home bed supply ~~if~~AND ~~the applicant demonstrates~~ all of the following REQUIREMENTS ARE MET:

~~(a) An existing nursing home may relocate no more than 50% of its beds to another existing nursing home, and an existing HLTCU may relocate all or a portion of its beds to another existing nursing home/HLTCU.~~

(~~b~~a) THERE SHALL NOT BE ANY OWNERSHIP RELATIONSHIP REQUIREMENTS BETWEEN ~~T~~the nursing home/HLTCU from which the beds are being relocated and the nursing home/HLTCU receiving the beds ~~shall not require any ownership relationship~~.

(~~c~~b) THE RELOCATED BEDS SHALL BE PLACED~~The nursing home/HLTCU from which the beds are being relocated and the nursing home/HLTCU receiving the beds must be located~~ in the same planning area.

~~(d) The nursing home/HLTCU from which the beds are being relocated has not relocated any beds within the last seven (7) years.~~

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

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

(e) RELOCATION OF BEDS SHALL NOT INCREASE THE ROOMS WITH THREE (3) OR MORE BED WARDS IN THE RECEIVING FACILITY.

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

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

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

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) ~~Outstanding~~DELINQUENT debt obligation to the State of Michigan INCLUDING, BUT NOT LIMITED TO, ~~for~~ Quality Assurance Assessment Program (QAAP), PREADMISSION SCREENING AND ANNUAL RESIDENT REVIEW (PASARR) or Civil Monetary Penalties (CMP).

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

(c) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health ~~Systems~~CARE SERVICES within ~~the~~

~~Department~~LARA. Code deficiencies include any unresolved deficiencies still outstanding with ~~the~~ ~~Department~~LARA.

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

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

(1) An applicant proposing to acquire an existing nursing home/HLTCU shall not be required to be in compliance with the needed nursing home bed supply ~~set forth in Appendix B~~ for the planning area in which the nursing home or HLTCU is located ~~if~~ AND ~~the applicant demonstrates~~ all of the following REQUIREMENTS ARE MET:

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

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

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) ~~Outstanding~~ DELINQUENT debt obligation to the state of Michigan INCLUDING, BUT NOT LIMITED TO, ~~for~~ quality assurance assessment program (QAAP), PREADMISSION SCREENING AND ANNUAL RESIDENT REVIEW (PASARR) OR civil monetary penalties (CMP).

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

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

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

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

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

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

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

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

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) ~~Outstanding~~ DELINQUENT debt obligation to the State of Michigan INCLUDING, BUT NOT LIMITED TO, ~~for~~ Quality Assurance Assessment Program (QAAP), PREADMISSION SCREENING AND ANNUAL RESIDENT REVIEW (PASARR) or Civil Monetary Penalties (CMP).

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

(c) The applicant shall participate in a quality improvement program, approved by the Department, for five years and provide an annual report to the Michigan State Long-Term-Care Ombudsman, Bureau

of Health ~~Systems~~OF HEALTH CARE SERVICES WITHIN LARA, and shall post the annual report in the facility if the facility being acquired has met any of conditions in subsections (a)(i), (ii), (iii), (iv), (v), or (vi).

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

(3) An applicant proposing to renew the lease for an existing nursing home/HLTCU shall not be required to be in compliance with the needed nursing home bed supply ~~set forth in Appendix B~~ for the planning area in which the nursing home/HLTCU is located, ~~if~~ AND ~~the applicant demonstrates~~ all of the following REQUIREMENTS ARE MET:

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

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

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

Section 10. Review standards for comparative review

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

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

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

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

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

Percentage of Medicaid Patient Days (calculated using total patient days for all existing and proposed beds at the facility)	Points Awarded	
	~~Current~~ EXISTING	Proposed
~~20~~ 50 – ~~59~~69%	~~6~~4	3
~~60~~ 70 – 100%	~~10~~8	~~5~~7

(b) A qualifying project will be awarded 10 points ~~as follows:~~

~~(i) For an existing nursing home/HLTCU, nine (9) points if 100%, six (6) points if 75%, and four (4) points if 50% of the licensed nursing home beds are Medicaid certified for the most recent 12 months of operations.~~

~~(ii) For a new nursing home/HLTCU, seven (7) points if 100%, four (4) points if 75%, and two (2) points if 50% of the proposed beds will be Medicaid certified by the second 12 months of operation following project completion~~IF ALL BEDS IN THE PROPOSED PROJECT WILL BE DUALLY CERTIFIED FOR BOTH MEDICARE AND MEDICAID SERVICES BY THE SECOND 12 MONTHS OF OPERATION.

(3) A qualifying project will be awarded points based on the most recent 12 months of participation level in the Medicare program for an existing nursing home/HLTCU and the proposed participation level for a new nursing home/HLTCU.

Participation Level	Points Awarded
Medicare certification of at least one (1) bed but less than 100%	1
Medicare certification of 100% of all existing and proposed beds	3

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

(a) is currently a special focus nursing home/HLTCU as identified by the Centers for Medicare and Medicaid Services (CMS);

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

(cb) 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);

(dc) 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;

(ed) 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

(fe) has any outstanding DELINQUENT debt obligation to the state of Michigan INCLUDING, BUT NOT LIMITED TO, for quality assurance assessment program (QAAP), civil monetary penalties (CMP), Medicaid level of care determination (LOCD), or preadmission screening and annual resident review (PASARR).

(54) A qualifying project will be awarded 10 THREE (3) points if the applicant provides documentation that it participates or five (5) points if it proposes to participate in a culture change model, which contains person centered care, ongoing staff training, and measurements of outcomes. An additional five (5) points will be awarded if the culture change model, either currently used or proposed, is a model approved by the Department.

(65) 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

(76) A qualifying project will be awarded five (5) points if the existing or proposed nursing home/HLTCU is fully equipped with sprinklers.

(8) A qualifying project will be awarded five FOUR (54) points if the ENTIRE existing or AND proposed nursing home/HLTCU is fully equipped with air conditioning AS DEFINED IN THE 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~~. FULLY EQUIPPED WITH AIR CONDITIONING MEANS MEETING THE DESIGN TEMPERATURES IN TABLE 6B OF THE MINIMUM DESIGN STANDARDS FOR HEALTH CARE FACILITIES IN MICHIGAN AND CAPABLE OF MAINTAINING A TEMPERATURE OF 71 – 81 DEGREES FOR THE RESIDENT UNIT CORRIDORS.

(~~9~~7) A qualifying project will be awarded SIX (6) OR FOUR (4) points based on ~~the proposed project as follows~~ONLY ONE OF THE FOLLOWING:

(a) SIX (6) POINTS IF THE PROPOSED PROJECT HAS 100% ~~private~~ rooms with DEDICATED TOILET ROOM CONTAINING A sink, WATER CLOSET, and ~~shower~~ BATHING FACILITY OR

(b) FOUR (4) POINTS IF THE PROPOSED PROJECT HAS 80% private rooms with dedicated TOILET ROOM CONTAINING A SINK, WATER CLOSET and ~~shower~~BATHING FACILITY.

~~Facility Design~~	~~Points Awarded~~
~~100% private rooms with adjoining sink, toilet, and shower~~	~~10~~
~~100% private rooms with dedicated and shared adjoining toilet, sink and shower~~	~~5~~
~~80% private rooms with dedicated sink, shared adjoining toilet and sink, and central showers with adjoining space for drying and dressing in visual privacy~~	~~3~~

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

~~(11) A qualifying project will be awarded five (5) points if the applicant provides its audited financial statements.~~

(~~12~~9) A qualifying project will be awarded five (5) points if the proposed beds will be housed in new construction.

(~~13~~10) A qualifying project will be awarded 10 points if the ENTIRE existing ~~AND PROPOSED~~ nursing home/HLTCU AND ITS PROPOSED PROJECT ~~eliminates all of its 3- and 4-bed wards~~WILL HAVE NO MORE THAN DOUBLE OCCUPANCY ROOMS AT COMPLETION OF THE PROJECT.

(~~14~~11) A qualifying project will be awarded ~~5~~ TWO (2) points if the existing or proposed nursing home/HLTCU is on or readily accessible to an existing or proposed public transportation route.

(~~15~~12) A qualifying project will be awarded ~~no more than four (4)~~ points for technological innovation as follows:

~~Technology Feature~~INNOVATIONS	Points Awarded
THE PROPOSED PROJECT WILL HAVE wireless nurse call/paging system including wireless devices carried by direct care staff~~Electronic health record and computer point-of-service entry capability (including wireless tablets)~~	1
WIRELESS INTERNET WITH RESIDENT ACCESS TO RELATED EQUIPMENT/DEVICE IN ENTIRE FACILITY~~Wireless nurse call/paging system including~~	1

~~wireless devices carried by direct care staff~~	
AN INTEGRATED ELECTRONIC MEDICAL RECORDS SYSTEM WITH POINT-OF-SERVICE ACCESS CAPABILITY (INCLUDING WIRELESS DEVICES) FOR ALL DISCIPLINES INCLUDING PHARMACY, PHYSICIAN, NURSING, AND THERAPY SERVICES AT THE ENTIRE EXISTING AND PROPOSED NURSING HOME/HLTCU~~Wireless internet in total existing and proposed facility~~	~~1~~4
~~Computer stations or internet cafes for resident use~~	~~1~~
THE PROPOSED PROJECT WILL HAVE A BACKUP GENERATOR SUPPORTING ALL FUNCTIONS WITH AN ON-SITE OR PIPED-IN FUEL SUPPLY AND BE CAPABLE OF PROVIDING AT LEAST 48 HOURS OF SERVICE AT FULL LOAD	4

(~~16~~13) A QUALIFYING PROJECT WILL BE AWARDED THREE (3) POINTS IF THE PROPOSED PROJECT INCLUDES BARIATRIC ROOMS AS FOLLOWS: PROJECT USING 0 – 49 BEDS WILL RESULT IN AT LEAST ONE (1) BARIATRIC ROOM OR PROJECT USING 50 OR MORE BEDS WILL RESULT IN AT LEAST TWO (2) BARIATRIC ROOMS. BARIATRIC ROOM MEANS THE CREATION OF PATIENT ROOM(S) INCLUDED AS PART OF THE CON PROJECT, AND IDENTIFIED ON THE ARCHITECTURAL SCHEMATICS, THAT ARE DESIGNED TO ACCOMMODATE THE NEEDS OF BARIATRIC PATIENTS WEIGHING OVER 400 POUNDS. THE BARIATRIC PATIENT ROOMS SHALL HAVE A LARGER ROOM AND BATHROOM ENTRANCE WIDTH TO ACCOMMODATE OVER-SIZED EQUIPMENT, AND SHALL INCLUDE A MINIMUM OF A BARIATRIC BED, BARIATRIC TOILET, BARIATRIC WHEELCHAIR, AND A DEVICE TO ASSIST RESIDENT MOVEMENT (SUCH AS A PORTABLE OR BUILD IN LIFT). IF AN IN-ROOM SHOWER IS NOT INCLUDED IN THE BARIATRIC PATIENT ROOM, THE MAIN/CENTRAL SHOWER ROOM THAT IS LOCATED ON THE SAME FLOOR AS THE BARIATRIC PATIENT ROOM(S) SHALL INCLUDE AT LEAST ONE (1) SHOWER STALL THAT HAS AN OPENING WIDTH AND DEPTH THAT IS LARGER THAN MINIMUM MI CODE REQUIREMENTS.

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

(~~17~~15) The Department shall approve those qualifying projects which, when taken together, do not exceed the need as defined in Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws, and which have the highest number of points when the results of subsections (2) through (~~15~~12) are totaled. If two or more qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section 22225(1), in the order in which the applications were received by the Department, based on the date and time stamp on the application when the application is filed.

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

Sec. 11. ~~(1)~~ An applicant shall agree that, if approved, the ~~project~~ NURSING HOME/HLTCU SERVICES shall be delivered in compliance with the following terms of ~~CON~~ approval:

(~~a~~1) Compliance with these standards, including the requirements of Section 10. IF AN APPLICANT IS AWARDED BEDS PURSUANT TO SECTION 10 AND REPRESENTATIONS MADE IN THAT SECTION, THE DEPARTMENT SHALL MONITOR COMPLIANCE WITH THOSE STATEMENTS AND REPRESENTATIONS AND SHALL DETERMINE ACTIONS FOR NON-COMPLIANCE.

(~~b~~2) COMPLIANCE WITH THE FOLLOWING APPLICABLE QUALITY ASSURANCE STANDARDS:

(a) Compliance with Section 22230 of the Code shall be based on the nursing home's/HLTCU's actual Medicaid participation within the time periods specified in these standards. Compliance with Section 10(2)(a) of these standards shall be determined by comparing the nursing home's/HLTCU's actual patient days reimbursed by Medicaid, as a percentage of the total patient days, with the applicable schedule set forth in Section 10(2)(a) for which the applicant had been awarded points in the comparative review process. If any of the following occurs, an applicant shall be required to be in compliance with the range in the schedule immediately below the range for which points had been awarded in Section 10(2)(a), instead of the range of points for which points had been awarded in the comparative review in order to be found in compliance with Section 22230 of the Code: (i) the average percentage of Medicaid recipients in all nursing homes/HLTCUs in the planning area decreased by at least 10 percent between the second 12 months of operation after project completion and the most recent 12-month period for which data are available, (ii) the actual rate of increase in the Medicaid program per diem reimbursement to the applicant nursing home/HLTCU is less than the annual inflation index for nursing homes/HLTCUs as defined in any current approved Michigan State Plan submitted under Title XIX of the Social Security Act which contains an annual inflation index, or (iii) the actual percentage of the nursing home's/HLTCU's patient days reimbursed by Medicaid (calculated using total patient days for all existing and proposed nursing home beds at the facility) exceeds the statewide average plus 10 percent of the patient days reimbursed by Medicaid for the most recent year for which data are available from the Michigan Department of Community Health [subsection (iii) is applicable only to Section 10(2)(a)]. In evaluating subsection (ii), the Department shall rely on both the annual inflation index and the actual rate increases in per diem reimbursement to the applicant nursing home/HLTCU and/or all nursing homes/HLTCUs in the HSA.

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

~~(d) Compliance with applicable operating standards.~~

~~(e) Compliance with the following quality assurance standards:~~

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

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

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

(a) THE APPLICANT, TO ASSURE APPROPRIATE UTILIZATION BY ALL SEGMENTS OF THE MICHIGAN POPULATION, SHALL:

(i) NOT DENY SERVICES TO ANY INDIVIDUAL BASED ON PAYOR SOURCE.

(ii) MAINTAIN INFORMATION BY SOURCE OF PAYMENT TO INDICATE THE VOLUME OF CARE FROM EACH PAYOR AND NON-PAYOR SOURCE PROVIDED ANNUALLY.

(iii) PROVIDE SERVICES TO ANY INDIVIDUAL BASED ON CLINICAL INDICATIONS OF NEED FOR THE SERVICES.

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

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

(iv) The applicant shall provide the Department with ~~a~~ TIMELY notice ~~stating the date the beds are placed in operation and such notice shall be submitted to the Department~~ OF THE PROPOSED PROJECT IMPLEMENTATION consistent with applicable statute and promulgated rules.

(~~2~~5) An applicant shall agree that, if approved, and material discrepancies are later determined within the reporting of the ownership and citation history of the applicant facility and all nursing homes under common ownership and control that would have resulted in a denial of the application, shall surrender the CON. This does not preclude an applicant from reapplying with corrected information at a later date.

(~~3~~6) The agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant or its authorized agent.

Section 12. Department inventory of beds

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

Section 13. Wayne County planning areas

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

Planning Area 84/Northwest Wayne

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

Planning area 85/Southwest Wayne

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

Planning area 86/Detroit

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

~~**Section 14. Health Service Areas**~~

~~Sec. 14. Counties assigned to each of the HSAs are as follows:~~

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

~~Delta~~ ~~Keweenaw~~ ~~Ontonagon~~
~~Dickinson~~ ~~Luce~~ ~~Schoolcraft~~

Section 15. Effect on prior CON review standards, comparative reviews

Sec. 15. (1) These CON review standards supersede and replace the CON Standards for Nursing Home and Hospital Long-Term-Care Unit (HLTCU) Beds approved by the CON Commission on ~~April 30, 2008~~DECEMBER 15, 2010 and effective on ~~June 20, 2008~~MARCH 11, 2011.

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

(a) replacement of an existing nursing home/HLTCU being replaced in a rural county;

(b) replacement of an existing nursing home/HLTCU in a micropolitan or metropolitan statistical area county that is within two miles of the existing nursing home/HLTCU;

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

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

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

APPENDIX A

Counties assigned to each of the HSAs are as follows:

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

APPENDIX ~~AB~~

CON REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT BEDS

The use rate per 1000 population for each age cohort, for purposes of these standards, effective ~~March~~ AUGUST 1~~1~~, ~~2011~~2013, and until otherwise changed by the Commission, is as follows.

(i) Age 0 - 64: ~~208~~ 200 days of care

(ii) Age 65 - 74: ~~2,791~~ 2,638 days of care

(iii) Age 75 - 84: ~~10,047~~9379 days of care

(iv) Age 85 +: ~~36,758~~34,009 days of care

APPENDIX ~~BC~~

CON REVIEW STANDARDS FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT BEDS

The ~~bed need numbers~~ADC ADJUST FACTOR, for purposes of these standards, effective ~~TBD~~AUGUST 1, 2013, and until otherwise changed by the Commission, are as follows:

Planning Area	~~Bed Need~~	ADC Adjustment Factor
Alcona	~~115~~	0.~~95~~90
Alger	~~65~~	0.90
Allegan	~~500~~	0.95
Alpena	~~187~~	0.95
Antrim	~~168~~	0.95
Arenac	~~100~~	0.~~95~~90
Baraga	~~58~~	0.90
Barry	~~275~~	0.95
Bay	~~603~~	0.95
Benzie	~~124~~	0.95
Berrien	~~884~~	0.95
Branch	~~224~~	0.95
Calhoun	~~675~~	0.95
Cass	~~273~~	0.95
Charlevoix	~~159~~	0.95
Cheboygan	~~188~~	0.95
Chippewa	~~202~~	0.95
Clare	~~185~~	0.95
Clinton	~~319~~	0.95
Crawford	~~95~~	0.90
Delta	~~245~~	0.95
Dickinson	~~190~~	0.95
Eaton	~~491~~	0.95
Emmet	~~201~~	0.95
Genesee	~~1,880~~	0.95
Gladwin	~~184~~	0.95
Gogebic	~~137~~	0.95
Gd. Traverse	~~455~~	0.95
Gratiot	~~209~~	0.95
Hillsdale	~~233~~	0.95
Houghton/Keweenaw	~~222~~	0.95
Huron	~~237~~	0.95

1126

APPENDIX ~~B~~ C - continued

Planning Area	~~Bed Need~~	ADC Adjustment Factor
Ingham	~~1,048~~	0.95
Ionia	~~260~~	0.95
Iosco	~~204~~	0.95
Iron	~~120~~	0.~~95~~90
Isabella	~~245~~	0.95
Jackson	~~777~~	0.95
Kalamazoo	~~1,077~~	0.95
Kalkaska	~~95~~	0.90
Kent	~~2,451~~	0.95
Lake	~~88~~	0.90
Lapeer	~~375~~	0.95
Leelanau	~~159~~	0.95
Lenawee	~~524~~	0.95
Livingston	~~710~~	0.95
Luce	~~36~~	0.90
Mackinac	~~78~~	0.90
Macomb	~~4,255~~	0.95
Manistee	~~169~~	0.95
Marquette	~~338~~	0.95
Mason	~~186~~	0.95
Mecosta	~~220~~	0.95
Menominee	~~167~~	0.95
Midland	~~411~~	0.95
Missaukee	~~92~~	0.90
Monroe	~~686~~	0.95
Montcalm	~~291~~	0.95
Montmorency	~~101~~	0.~~95~~90
Muskegon	~~843~~	0.95
Newaygo	~~241~~	0.95
Oakland	~~5,630~~	0.95
Oceana	~~152~~	0.95
Ogemaw	~~134~~	0.95
Ontonagon	~~59~~	0.90
Osceola	~~127~~	0.95
Oscoda	~~72~~	0.90
Otsego	~~132~~	0.95
Ottawa	~~1,145~~	0.95

APPENDIX B - continued

Planning Area	~~Bed Need~~	ADC Adjustment Factor
Presque Isle	~~124~~	0.95
Roscommon	~~227~~	0.95
Saginaw	~~1,038~~	0.95
St. Clair	~~811~~	0.95
St. Joseph	~~290~~	0.95
Sanilac	~~250~~	0.95
Schoolcraft	~~61~~	0.90
Shiawassee	~~336~~	0.95
Tuscola	~~287~~	0.95
Van Buren	~~365~~	0.95
Washtenaw	~~1,268~~	0.95
Wexford	~~170~~	0.95
NW Wayne	~~2,305~~	0.95
SW Wayne	~~1,542~~	0.95
Detroit	~~4,140~~	0.95
~~**Statewide Total**~~	~~**46,995**~~	

APPENDIX ~~CD~~

~~CON REVIEW STANDARDS~~
~~FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT BEDS~~

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

APPENDIX ~~D~~E

CON REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS

Michigan nursing home planning areas with a population density of less than 28 individuals per square mile based on ~~2000~~ 2010 U.S. Census figures.

Planning Area	Population Density Per Square Mile
Ontonagon	~~6.0~~5.11
Schoolcraft	~~7.6~~6.95
Luce	~~7.8~~7.16
Baraga	~~9.7~~9.67
~~Alger~~IRON	~~10.7~~9.76
~~Iron~~ALGER	~~11.3~~10.25
Mackinac	~~11.7~~10.45
~~Oscoda~~GOGEBIC	~~16.7~~14.35
~~Alcona~~OSCODA	~~17.4~~15.12
~~Gogebic~~ALCONA	~~15.8~~15.76
Montmorency	~~18.8~~17.36
~~Lake~~PRESQUE ISLE	~~20.0~~19.53
~~Presque isle~~LAKE	~~21.8~~20.11
~~Menominee~~CHIPPEWA	~~24.3~~21.29
~~Chippewa~~MENOMINEE	~~24.7~~22.86
Houghton/Keweenaw	~~24.7~~24.17
~~Missaukee~~CRAWFORD	~~25.5~~25.00
~~Crawford~~MISSAUKEE	~~25.6~~25.90

Source: Michigan Department of Management and Budget and the U.S. Bureau of the Census

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

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

Section 1. Applicability; definitions

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

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

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

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

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

(b) "Hospice" means a health care program licensed under Part 214 of the Code, being Section 333.21401 et seq.

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

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

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

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

(g) "Ventilator-dependent patient," means an individual who requires mechanical ventilatory assistance.

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

Sec. 2. A project to increase nursing home beds in a planning area which, if approved, would otherwise cause the total number of nursing home beds in that planning area to exceed the needed nursing home bed supply or cause an increase in an existing excess as determined under the applicable

CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds, may nevertheless be approved pursuant to this addendum.

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

Sec. 3. (1) A statewide pool of additional nursing home beds of 1,958 beds needed in the state is established to better meet the needs of special population groups within the long-term care and nursing home populations. Beds in the pool shall be allocated as follows:

(a) These categories shall be allocated 1,109 beds and distributed as follows and shall be reduced/redistributed in accordance with subsection (c):

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

(ii) Behavioral beds will be allocated 400 beds.

(iii) Hospice beds will be allocated 130 beds.

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

(b) The following historical categories have been allocated 849 beds. Additional beds shall not be allocated to these categories. If the beds within any of these categories are delicensed, the beds shall be eliminated and not be returned to the statewide pool for special population groups.

(i) Alzheimer's disease has 384 beds.

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

(iii) Religious has 292 beds.

(c) The number of beds set aside from the total statewide pool established for categories in subsection (1)(a) for a special population group shall be reduced if there has been no CON activity for that special population group during at least 6 consecutive application periods.

(i) The number of beds in a special population group shall be reduced to the total number of beds for which a valid CON has been issued for that special population group.

(ii) The number of beds reduced from a special population group pursuant to this subsection shall revert to the total statewide pool established for categories in subsection (1)(a).

(iii) The Department shall notify the Commission of the date when action to reduce the number of beds set aside for a special population group has become effective and shall identify the number of beds that reverted to the total statewide pool established for categories in subsection (1)(a).

(iv) For purposes of this subsection, "application period" means the period of time from one designated application date to the next subsequent designated application date.

(v) For purposes of this subsection, "CON activity" means one or more of the following:

(A) CON applications for beds for a special population group have been submitted to the Department for which either a proposed or final decision has not yet been issued by the Department.

(B) Administrative hearings or appeals to court of decisions issued on CON applications for beds for a special population group are pending resolution.

(C) An approved CON for beds for each special population group has expired for lack of appropriate action by an applicant to implement an approved CON.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sec. 6. The CON Commission determines there is a need for beds for patients requiring both hospice and long-term nursing care services within the long-term care and nursing home populations.

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

(a) An applicant shall be a hospice certified by Medicare pursuant to the Code of Federal Regulations, Title 42, Chapter IV, Subpart B (Medicare programs), Part 418 and shall have been a Medicare certified hospice for at least 24 continuous months prior to the date an application is submitted to the Department.

(b) An applicant shall demonstrate that, during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable data are available to the Department, at least 64% of the total number of hospice days of care provided to all of the clients of the applicant hospice were provided in a private residence.

(c) An application shall propose 30 beds or less.

(d) An applicant for beds from the special statewide pool of beds shall not be approved if any application for beds in that same planning area has been approved from the special statewide pool of beds allocated for hospice.

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

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

Sec. 7. The CON Commission determines there is a need for beds for ventilator-dependent patients within the long-term care and nursing home populations

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to Alzheimer’s disease shall meet the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) An applicant shall be a hospice certified by Medicare pursuant to the code of Federal Regulations, Title 42, Chapter IV, Subpart B (Medicare Programs), Part 418 and shall have been a Medicare certified hospice for at least 24 continuous months prior to the date an application is submitted to the Department.

(b) An applicant shall demonstrate that, during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable data are available to the Department, at least 64% of the total number of hospice days of care provided to all of the clients of the applicant hospice were provided in a private residence.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) An applicant shall maintain Medicare certification of the hospice program and shall establish and maintain the ability to provide, either directly or through contractual arrangements, hospice services as outlined in the Code of Federal Regulations, Title 42, Chapter IV, Subpart B, Part 418, hospice care.

(b) The proposed project shall be designed to promote a home-like atmosphere that includes accommodations for family members to have overnight stays and participate in family meals at the applicant facility.

(c) An applicant shall not refuse to admit a patient solely on the basis that he/she is HIV positive, has AIDS or has AIDS related complex.

(d) An applicant shall make accommodations to serve patients that are HIV positive, have AIDS or have AIDS related complex in nursing home beds.

(e) An applicant shall make accommodations to serve children and adolescents as well as adults in nursing home beds.

(f) Nursing home beds shall only be used to provide services to individuals suffering from a disease or condition with a terminal prognosis in accordance with Section 21417 of the Code, being Section 333.21417 of the Michigan Compiled Laws.

(g) An applicant shall agree that the nursing home beds shall not be used to serve individuals not meeting the provisions of Section 21417 of the Code, being Section 333.21417 of the Michigan Compiled Laws, unless a separate CON is requested and approved pursuant to applicable CON review standards.

(h) An applicant shall be licensed as a hospice program under Part 214 of the Code, being Section 333.21401 et seq. of the Michigan Compiled Laws.

(i) An applicant shall agree that at least 64% of the total number of hospice days of care provided by the applicant hospice to all of its clients will be provided in a private residence.

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

(a) An applicant shall staff the proposed ventilator-dependent unit with employees that have been trained in the care and treatment of ventilator-dependent patients and includes at least the following:

(i) A medical director with specialized knowledge, training, and skills in the care of ventilator-dependent patients.

(ii) A program director that is a registered nurse.

(b) An applicant shall make provisions, either directly or through contractual arrangements, for at least the following services:

(i) respiratory therapy.

(ii) occupational and physical therapy.

(iii) psychological services.

(iv) family and patient teaching activities.

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

(i) Patient admission criteria that describe minimum and maximum characteristics for patients appropriate for admission to the ventilator-dependent unit. At a minimum, the criteria shall address the amount of mechanical ventilatory dependency, the required medical stability, and the need for ancillary services.

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

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

(iv) Patient rights and responsibilities in accordance with Sections 20201 and 20202 of the Code, being Sections 333.20201 and 333.20202 of the Michigan Compiled Laws.

(v) The type of ventilatory equipment to be used on the unit and provisions for back-up equipment.

(d) An applicant shall establish and maintain an organized infection control program that has written policies for each of the following:

(i) use of intravenous infusion apparatus, including skin preparation, monitoring skin site, and frequency of tube changes.

(ii) placement and care of urinary catheters.

(iii) care and use of thermometers.

(iv) care and use of tracheostomy devices.

(v) employee personal hygiene.

(vi) aseptic technique.

(vii) care and use of respiratory therapy and related equipment.

(viii) isolation techniques and procedures.

(e) An applicant shall establish a multi-disciplinary infection control committee that meets on at least a monthly basis and includes the director of nursing, the ventilator-dependent unit program director, and representatives from administration, dietary, housekeeping, maintenance, and respiratory therapy. This subsection does not require a separate committee, if an applicant organization has a standing infection control committee and that committee's charge is amended to include a specific focus on the ventilator-dependent unit.

(f) The proposed ventilator-dependent unit shall have barrier-free access to an outdoor area in the immediate vicinity of the unit.

(g) An applicant shall agree that the beds will not be used to service individuals that are not ventilator-dependent unless a separate CON is requested and approved by the Department pursuant to applicable CON review standards.

(h) An applicant shall provide data to the Department that evaluates the cost efficiencies that result from providing services to ventilator-dependent patients in a hospital.

(6) An applicant for beds from the statewide pool for special population groups allocated to TBI/SCI patients shall agree that if approved:

(a) An applicant shall staff the proposed unit for TBI/SCI patients with employees that have been trained in the care and treatment of such individuals and includes at least the following:

(i) A medical director with specialized knowledge, training, and skills in the care of TBI/SCI patients.

(ii) A program director that is a registered nurse.

(iii) Other professional disciplines required for a multi-disciplinary team approach to care.

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

(i) Patient admission criteria that describe minimum and maximum characteristics for patients appropriate for admission to the unit for TBI/SCI patients. At a minimum, the criteria shall address the required medical stability and the need for ancillary services, including dialysis services.

(ii) The transfer of patients requiring care at other health care facilities, including a transfer agreement with one or more acute-care hospitals in the region to provide emergency medical treatment to any patient who requires such care.

(iii) Upon admission and periodically thereafter, a comprehensive needs assessment, a treatment plan, and a discharge plan that at a minimum addresses the care needs of a patient following discharge, including support services to be provided by transitional living programs or other outpatient programs or services offered as part of a continuum of care to TBI patients by the applicant.

(iv) Utilization review, which shall consider the rehabilitation necessity for the service, quality of patient care, rates of utilization and other considerations generally accepted as appropriate for review.

(v) Quality assurance and assessment program to assure that services furnished to TBI/SCI patients meet professional recognized standards of health care for providers of such services and that such services were reasonable and medically appropriate to the clinical condition of the TBI patient receiving such services.

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

(a) An applicant shall staff the proposed unit for behavioral patients with employees that have been trained in the care and treatment of such individuals and includes at least the following:

(i) A medical director with specialized knowledge, training, and skills in the care of behavioral patients.

(ii) A program director that is a registered nurse.

(iii) Other professional disciplines required for a multi-disciplinary team approach to care.

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

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

(ii) The transfer of patients requiring care at other health care facilities, including a transfer agreement with one or more acute-care hospitals in the region to provide emergency medical treatment to any patient who requires such care.

(iii) Utilization review, which shall consider the rehabilitation necessity for the service, quality of patient care, rates of utilization and other considerations generally accepted as appropriate for review.

(iv) quality assurance and assessment program to assure that services furnished to behavioral patients meet professional recognized standards of health care for providers of such services and that such services were reasonable and medically appropriate to the clinical condition of the behavioral patient receiving such services.

(v) Orientation and annual education/competencies for all staff, which shall include care guidelines, specialized communication, and patient safety.

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

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

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

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

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

(5) These CON review standards supercede and replace the CON Review Standards for Nursing Home and Long-term Care Unit Beds--Addendum for Special Population Groups approved by the Commission on April 30, 2008 and effective on June 20, 2008.

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Background

Henry Ford Hospital's vision to establish a Rehabilitation Center of Excellence in Detroit began in March of 2012. This center of excellence would include a 60 bed inpatient rehabilitation hospital, a comprehensive outpatient physical therapy clinic and a specialized ambulatory stroke clinic. The center of excellence is not simply a facilities project, but it is meant to add new clinical programming at our flagship hospital not currently provided within the Henry Ford Health System. We have modeled our plans upon the clinical excellence program at the Kessler Institute of Rehabilitation, which has been ranked #2 in US News & World Report for the last five years. The projected benefits of the Rehabilitation Center of Excellence are the following:

- Improved continuity of care within the Henry Ford Health System, which will improve patient outcomes.
- New clinical programs that will provide care locally to those who need it within the community
- The addition of this program will better position HFHS for value-based contracting and shared risk.
- Economic benefit to the City of Detroit for those patients who travel from greater than 50 miles to receive specialized care. Hotel stays, food purchases, etc. will all be generated by the creation of a Center of Excellence.

The reason we are proposing to build the facility across the street from the existing hospital is because we have no more space on the existing campus. We are still transitioning to private rooms in many specialties and we have prioritized this due to its direct correlation with patient satisfaction.

HFHS started meeting with the Michigan Department of Community Health to explain the project and determine if there were any concerns back in November of 2012. At that time it was determined that Certificate of Need interprets the Hospital Bed standards to require a physical connection between all buildings under a single hospital license. HFHS engaged our facilities staff as well as outside contractors to determine the cost of connecting the proposed addition across W. Grand Blvd. to the existing hospital and determined it would be a minimum of $12 million and potentially as expensive as $20 million. Because we felt the cost was unnecessary to provide appropriate care at the facility, we engaged the Michigan Department of Community Health and Michigan Department of Licensing and Regulatory Affairs (LARA) in further discussion on the issue throughout 2013.

Ultimately in October 2013 LARA requested that HFHS take this issue to the CON Commission for a more definitive and clear solution. In October 2013 HFHS submitted comments during the open comment period for standards up for review in 2014. We requested that the Commission review this issue along with adding hospital within a hospital (HIH) inpatient rehab facilities (IRFs) to the current section that pertains to HIH LTACHs. At the January 2014 Commission meeting, the Commission asked the Department to work with HFHS and bring back a recommendation and language regarding these concerns.

Hospital Bed Replacement

The Certificate of Need Standards for Hospital Beds allow for the replacement of a portion of a hospital's beds on the same existing licensed site. The standards define "licensed site" as "the location of the facility authorized by license and listed on that licensee's certificate of

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licensure." It does not specifically speak to a physical connection between all structured associated with the facility. However, the Department has historically interpreted this to require a physical connection.

Although I'm sure there are situations where having a portion of a hospital that is not physically connected to the rest of the hospital that would not make sense operationally, there are certainly examples where it has no impact on patient care. As part of the licensure process, the facility must submit an operational narrative, along with their proposed construction plans, to the Health Facilities Engineering Section within the Department of Licensing and Regulatory Affairs. It is their responsibility to determine if the construction project proposed will work for the intended operational use of the facility, as well as making sure all physical licensing requirements are met within the plans. If they do not feel it does meet all requirements, they will not issue a construction permit for the project.

For those projects where operationally a physical connection is not required, the ability to move forward with the project without it will save millions of dollars. For close to 100 years, Henry Ford Hospital has been a diligent steward of the health care resources available to meet the needs of the communities we serve, including the City of Detroit. We feel these dollars could better spent on additional patient care initiatives.

Attached you will find proposed language which would clearly allow for the replacement of a portion of beds on the existing licensed site, including contiguous property or property separated by ONLY a road. This language has been drafted to make it clear that this would still be considered part of the existing licensed site, and therefore we believe a single license would be issued for both the current hospital as well as the beds replaced across the street.

HIH Inpatient Rehab Facilities

While you are considering revisions to the hospital bed standards, we would also request your consideration of language which would treat HIH Inpatient Rehab Facilities the same as HIH LTACHs under the CON standards. CMS regulations allow for Inpatient Rehab Facilities {IRFs) to utilize the hospital in a hospital {HIH) model under the section referenced in the current LTACH standards. Although it could be argued that the current CON definition of LTAC includes IRFs because of the reference, the Department felt it was prudent to update the standards to include a specific reference to IRFs in the standards and to more carefully define each.

Attached you will find proposed changes to the hospital bed standards to treat HIH IRFs the same as HIH LTACHs, allowing them to be set up within an existing licensed hospital through leasing the space and beds from the host hospital and contracting for support services from the host hospital. This will then allow them to apply for PPS-exemption with CMS, similar to the LTACH process.

Hospital Bed Replacement Proposed Language

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Section 2. Definitions
(v) "Licensed site" means the location of the facility authorized by license and listed on that licensee's certificate of licensure.

(kk) "Replace beds" means a change in the location of the licensed hospital, or the replacement of a portion of the licensed beds at the same EXISTING licensed site WHICH CAN INCLUDE CONTIGUOUS PROPERTY, OR PROPERTY THAT IS SEPARATED FROM THE EXISTING LICENSED HOSPITAL PROPERTY BY ONLY A ROAD AND ITS PUBLIC RIGHTS-OF-WAY. The hospital beds will be in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, etc.) within the replacement zone.

Section 7. Requirements for approval to replace beds
Sec. 7. (1) If the application involves the development of a new licensed site, an applicant proposing to replace beds in a hospital within the replacement zone shall demonstrate that the new beds in a hospital shall result in a hospital of at least 200 beds in a metropolitan statistical area county or 25 beds in a rural or micropolitan statistical area county. This subsection may be waived by the Department if the Department determines, in its sole discretion, that a smaller hospital is necessary or appropriate to assure access to health-care services.

(2) The applicant shall specify whether the proposed project is to replace the licensed hospital to a new site or to replace a portion of the licensed beds at the existing licensed site WHICH CAN INCLUDE CONTIGUOUS PROPERTY, OR PROPERTY THAT IS SEPARATED FROM THE EXISTING LICENSED HOSPITAL PROPERTY BY ONLY A ROAD AND ITS PUBLIC RIGHTS-OF-WAY.

(3) The applicant shall demonstrate that the new licensed site is in the replacement zone.

(4) The applicant shall comply with the following requirements, as applicable:
(a) The applicant's hospital shall have an average adjusted occupancy rate of 40 percent or above.
(b) If the applicant hospital does not have an average adjusted occupancy rate of 40 percent or above, then the applicant hospital shall reduce the appropriate number of licensed beds to achieve an average adjusted occupancy rate of 60 percent or above. The applicant hospital shall not exceed the number of beds calculated as follows:
(i) As of the date of the application, calculate the number of adjusted patient days during the most recent, consecutive 36-month period where verifiable data is available to the Department, and divide by .60.
(ii) Divide the result of subsection (i) above by 1095 (or 1096 if the 36-month period includes a leap year) and round up to the next whole number or 25, whichever is larger. This is the maximum number of beds that can be licensed at the licensed hospital site after the replacement.
(c) Subsection (4)(a) and (b) shall not apply to excluded hospitals.

(5) An applicant proposing replacement beds in the replacement zone shall not be required to be in compliance with the needed hospital bed supply if the application meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.

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HIH Inpatient Rehab Facilities Proposed Language

Section 2. Definitions
(V) "INPATIENT REHABILITATION HOSPITAL" OR "IRF HOSPITAL" MEANS A HOSPITAL THAT HAS BEEN APPROVED TO PARTICIPATE IN THE TITLE XVIII (MEDICARE) PROGRAM AS A PROSPECTIVE PAYMENT SYSTEM (PPS) EXEMPT INPATIENT REHABILITATION HOSPITAL IN ACCORDANCE WITH 42 CFR PART 412 SUBPART P.
(* Y) "Long-term (acute) care hospital" or "LTAC hospital" means a hospital has been approved to participate in the Title XVIII (Medicare) program as a prospective payment system (PPS) exempt LONG-TERM CARE hospital in accordance with 42 CFR Part 412 SUBPART O.

Section 6. Requirements for approval -- new beds in a hospital

(2) An applicant proposing to begin operation as a new LTAC hospital, IRF HOSPITAL, or alcohol and substance abuse hospital within an existing licensed, host hospital shall demonstrate that it meets all of the requirements of this subsection:
(a) If the LTAC OR IRF hospital applicant described in this subsection does not meet the Title XVIII requirements of the Social Security Act for exemption from PPS as an LTAC OR IRF hospital within 12 months after beginning operation, then it may apply for a six-month extension in accordance with R325.9403 of the CON rules. If the applicant fails to meet the Title XVIII requirements for PPS exemption as an LTAC OR IRF hospital within the 12 or 18-month period, then the CON granted pursuant to this section shall expire automatically.
(b) The patient care space and other space to establish the new hospital is being obtained through a lease arrangement and renewal of a lease between the applicant and the host hospital. The initial, renewed, or any subsequent lease shall specify at least £1Lof the following:
(i) That the host hospital shall delicense the same number of hospital beds proposed by the applicant for licensure in the new hospital or any subsequent application to add additional beds.
(ii) That the proposed new beds shall be for use in space currently licensed as part of the host hospital.
(iii) That upon non-renewal and/or termination of the lease, upon termination of the license issued under Part 215 of the act to the applicant for the new hospital, or upon noncompliance with the project delivery requirements or any other applicable requirements of these standards, the beds licensed as part of the new hospital must be disposed of by one of the following means:
(A) Relicensure of the beds to the host hospital. The host hospital must obtain a CON to acquire the LTAC OR IRF hospital. In the event that the host hospital applies for a CON to acquire the LTAC OR IRF hospital [including the beds leased by the host hospital to the LTAC OR IRF hospital] within six months following the termination of the lease with the LTAC OR IRF hospital, it shall not be required to be in compliance with the hospital bed supply if the host hospital proposes to add the beds of the LTAC OR IRF hospital to the host hospital's medical/surgical licensed capacity and the application meets all other applicable project delivery requirements. The beds must be used for general medical/surgical purposes. Such an application shall not be subject to comparative review and shall be processed under the procedures for non-substantive review (as this will not be considered an increase in the number of beds originally licensed to the applicant at the host hospital);
(B) Delicensure of the hospital beds; or
(C) Acquisition by another entity that obtains a CON to acquire the new hospital in its entirety and that entity must meet and shall stipulate to the requirements specified in Section 6(2).
(c) The applicant or the current licensee of the new hospital shall not apply, initially or subsequently, for CON approval to initiate any other CON covered clinical services; provided, however, that this section is not intended, and shall not be construed in a manner which would prevent the licensee from contracting and/or billing for medically necessary covered clinical services required by its patients under arrangements with its host hospital or any other CON approved provider of covered clinical services.
(d) The new licensed hospital shall remain within the host hospital.
(e) The new hospital shall be assigned to the same hospital group as the host hospital.
(f) The proposed project to begin operation of a new hospital, under this subsection, shall constitute a change in bed capacity under section 1(2) of these standards.

(g) The lease will not result in an increase in the number of licensed hospital beds in the hospital group.
{h) Applications proposing a new hospital under this subsection shall not be subject to comparative review.

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Henry Ford Hospital Campus Overview

Options for campus development include both north and south of West Grand Boulevard

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

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

Section 1. Applicability

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

Section 2. Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) The applicant provides a proposed route schedule.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 11. Requirements for a dedicated research fixed CT scanner

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(xiii) neonatology

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

(i) pediatric bone marrow transplant program

(ii) established pediatric sedation program

(iii) pediatric open heart program

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

Section 19. Requirements for Medicaid participation

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

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

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

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) The proposed site offers the following services:

(i) diagnostic cardiac catheterization; or

(ii) interventional radiology; or

(iii) surgical services

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

(i) cardiac catheterization lab; or

(ii) interventional radiology suite; or

(iii) licensed operating room

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 22. Determination of CT Equivalents

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

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

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

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

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

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

Section 23. Documentation of projections

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

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

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

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

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

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

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

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

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

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

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

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

APPENDIX A

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

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

APPENDIX B

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

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

Section 1. Applicability

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

Section 2. Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(mm) "Planning area" means

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

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

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

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

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

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

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

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

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

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

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

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

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

(~~tt~~qq) "Site" means

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

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

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

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

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

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

Section 3. Requirements to initiate an MRI service

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 4. Requirements to replace an existing MRI unit

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 5. Requirements to expand an existing MRI service

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

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

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

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

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

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

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

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

Section 7. Requirements to establish a dedicated research MRI unit

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

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

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

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

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

Section 8. Requirements to establish a dedicated pediatric MRI unit

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) has an implantable cardiac device.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 13. Requirements for all applicants

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

Section 14. Project delivery requirements – terms of approval

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

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 15. MRI procedure adjustments

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

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

(i) fMRI means brain activation studies.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 16. Documentation of actual utilization

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

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

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

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

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

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

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

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

(b) Identify the number of available MRI adjusted procedures, if any, for each existing MRI service as determined pursuant to Section 2(1)(c).

(c) Determine the number of available MRI adjusted procedures that each referring doctor may commit from each service to an application in accordance with the following:

(i) Divide the number of available MRI adjusted procedures identified in subsection (b) for each service by the number of actual MRI adjusted procedures identified in subsection (a) for that existing MRI service.

(ii) For each doctor referring to that existing service, multiply the number of actual MRI adjusted procedures that the referring doctor made to the existing MRI service by the applicable proportion obtained by the calculation in subdivision (c)(i).

(A) For each doctor, subtract any available adjusted procedures previously committed. The total for each doctor cannot be less than zero.

(B) The total number of available adjusted procedures for that service shall be the sum of the results of (A) above.

(iii) For each MRI service, the available MRI adjusted procedures resulting from the calculation in (c)(ii) above shall be sorted in descending order by the available MRI adjusted procedures for each doctor. Then any duplicate values shall be sorted in descending order by the doctors' license numbers (last 6 digits only).

(iv) Using the data produced in (c)(iii) above, sum the number of available adjusted procedures in descending order until the summation equals at least 75 percent of the total available adjusted procedures. This summation shall include the minimum number of doctors necessary to reach the 75 percent level.

(v) For the doctors representing 75 percent of the total available adjusted procedures in (c)(iv) above, sum the available adjusted procedures.

(vi) For the doctors used in subsection (c)(v) above, divide the total number of available adjusted procedures identified in (c)(ii)(B) above by the sum of those available adjusted procedures produced in (c)(v) above.

(vii) For only those doctors identified in (c)(v) above, multiply the result of (c)(vi) above by the available adjusted procedures calculated in (c)(ii)(A) above.

(viii) The result shall be the “Available MRI Adjusted Procedures List.”

(2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON applications received in which applicants apply for fixed MRI services pursuant to Section 3(2).

Section 18. Procedures and requirements for commitments of available MRI adjusted procedures

Sec. 18. (1) If one or more host sites on a mobile MRI service are located within the planning area of the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile MRI service.

(2)(a) At the time the application is submitted to the Department, the applicant shall submit a signed data commitment on a form provided by the Department in response to the applicant’s letter of intent for each doctor committing available MRI adjusted procedures to that application for a new MRI unit that requires doctor commitments.

(b) An applicant also shall submit, at the time the application is submitted to the Department, a computer file that lists, for each MRI service from which data are being committed to the same application, the name and license number of each doctor for whom a signed and dated data commitment form is submitted.

(i) The computer file shall be provided to the Department on mutually agreed upon media and in a format prescribed by the Department.

(ii) If the doctor commitments submitted on the Departmental forms do not agree with the data on the computer file, the applicant shall be allowed to correct only the computer file data which includes adding physician commitments that were submitted at the time of application.

(c) If the required documentation for the doctor commitments submitted under this subsection is not submitted with the application on the designated application date, the application will be deemed submitted on the first applicable designated application date after all required documentation is received by the Department.

(3) The Department shall consider a signed and dated data commitment on a form provided by the Department in response to the applicant’s letter of intent that meets the requirements of each of the following, as applicable:

(a) A committing doctor certifies that 100% of his or her available MRI adjusted procedures for each specified MRI service, calculated pursuant to Section 17, is being committed and specifies the CON application number for the MRI unit to which the data commitment is made. A doctor shall not be required to commit available MRI adjusted procedures from all MRI services to which his or her patients are referred for MRI services but only from those MRI services specified by the doctor in the data commitment form provided by the Department and submitted by the applicant in support of its application.

(b) A committing doctor certifies ownership interest, either direct or indirect, in the applicant entity. Indirect ownership includes ownership in an entity that has ownership interest in the applicant entity. This requirement shall not apply if the applicant entity is a group practice of which the committing doctor is a member. Group practice means a group practice as defined pursuant to the provisions of 42 U.S.C. 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411, published in the Federal Register on August 14, 1995, or its replacement.

(c) A committing doctor certifies that he or she has not been provided, or received a promise of being provided, a financial incentive to commit any of his or her available MRI adjusted procedures to the application.

(4)(a) The Department shall not consider a data commitment from a doctor for available MRI adjusted procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI service were used to support approval of an application for a new or additional MRI unit, pursuant to Section 3, for which a final decision to approve has been issued by the Director of the Department until either of the following occurs:

(i) The approved CON is withdrawn or expires.

(ii) The MRI service or unit to which the data were committed has been in operation for at least 36 continuous months.

(b) The Department shall not consider a data commitment from a doctor for available MRI adjusted procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI service were used to support an application for a new fixed or mobile MRI unit or additional mobile MRI unit pursuant to Section 3, for which a final decision to disapprove was issued by the Director of the Department until either of the following occurs:

(i) A final decision to disapprove an application is issued by the Director and the applicant does not appeal that disapproval or

(ii) If an appeal was made, either that appeal is withdrawn by the applicant or the committing doctor withdraws his or her data commitment pursuant to the requirements of subsection (8).

(5) The Department shall not consider a data commitment from a committing doctor for available MRI adjusted procedures from the same MRI service if that doctor has submitted a signed data commitment, on a form provided by Department, for more than one (1) application for which a final decision has not been issued by the Department. If the Department determines that a doctor has submitted a signed data commitment for the same available MRI adjusted procedures from the same MRI service to more than one CON application pending a final decision for a new fixed or mobile MRI unit or additional mobile MRI unit pursuant to Section 3, the Department shall,

(a) if the applications were submitted on the same designated application date, notify all applicants, simultaneously and in writing, that one or more doctors have submitted data commitments for available MRI adjusted procedures from the same MRI service and that the doctors' data from the same MRI service shall not be considered in the review of any of the pending applications submitted on the same designated application date until the doctor notifies the Department, in writing, of the one (1) application for which the data commitment shall be considered.

(b) if the applications were submitted on different designated application dates, consider the data commitment in the application submitted on the earliest designated application date and shall notify, simultaneously in writing, all applicants of applications submitted on designated application dates subsequent to the earliest date that one or more committing doctors have submitted data commitments for available MRI adjusted procedures from the same MRI service and that the doctors' data shall not be considered in the review of the application(s) submitted on the subsequent designated application date(s).

(6) The Department shall not consider any data commitment submitted by an applicant after the date an application is deemed submitted unless an applicant is notified by the Department, pursuant to subsection (5), that one or more committing doctors submitted data commitments for available MRI adjusted procedures from the same MRI service. If an applicant is notified that one or more doctors' data commitments will not be considered by the Department, the Department shall consider data commitments submitted after the date an application is deemed submitted only to the extent necessary to replace the data commitments not being considered pursuant to subsection (5).

(a) The applicant shall have 30 days to submit replacement of doctor commitments as identified by the Department in this Section.

(7) In accordance with either of the following, the Department shall not consider a withdrawal of a signed data commitment:

(a) on or after the date an application is deemed submitted by the Department.

(b) after a proposed decision to approve an application has been issued by the Department.

(8) The Department shall consider a withdrawal of a signed data commitment if a committing doctor submits a written notice to the Department, that specifies the CON application number and the specific MRI services for which a data commitment is being withdrawn, and if an applicant demonstrates that the requirements of subsection (7) also have been met.

Section 19. Lists published by the Department

Sec. 19. (1) On or before May 1 and November 1 of each year, the Department shall publish the following lists:

(a) A list, known as the "MRI Service Utilization List," of all MRI services in Michigan that includes at least the following for each MRI service:

(i) The number of actual MRI adjusted procedures;

(ii) The number of available MRI adjusted procedures, if any; and

(iii) The number of MRI units, including whether each unit is a clinical, research, or dedicated pediatric.

(b) A list, known as the "Available MRI Adjusted Procedures List," that identifies each MRI service that has available MRI adjusted procedures and includes at least the following:

(i) The number of available MRI adjusted procedures;

(ii) The name, address, and license number of each referring doctor, identified in Section 17(1)(c)(v), whose patients received MRI services at that MRI service; and

(iii) The number of available MRI adjusted procedures performed on patients referred by each referring doctor, identified in Section 17(1)(c)(v), and if any are committed to an MRI service. This number shall be calculated in accordance with the requirements of Section 17(1). A referring doctor may have fractional portions of available MRI adjusted procedures.

(c) For the lists published pursuant to subsections (a) or (b), the May 1 list will report 12 months of data from the previous January 1 through December 31 reporting period, and the November 1 list will report 12 months of data from the previous July 1 through June 30 reporting period. Copies of both lists shall be available upon request.

(d) The Department shall not be required to publish a list that sorts MRI database information by referring doctor, only by MRI service.

(2) When an MRI service begins to operate at a site at which MRI services previously were not provided, the Department shall include in the MRI database, data beginning with the second full quarter of operation of the new MRI service. Data from the start-up date to the start of the first full quarter will not be collected to allow a new MRI service sufficient time to develop its data reporting capability. Data from the first full quarter of operation will be submitted as test data but will not be reported in the lists published pursuant to this section.

(3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported data in compliance with the requirements of Section 14, the Department shall indicate on both lists that the MRI service is in violation of the requirements set forth in Section 14, and no data will be shown for that service on either list.

Section 20. Effect on prior CON Review Standards; Comparative reviews

Sec. 20. (1) These CON review standards supersede and replace the CON Review Standards for MRI Services approved by the CON Commission on June ~~14~~13, ~~2012~~ 2013 and effective September ~~28~~18, ~~2012~~2013.

(2) Projects reviewed under these standards shall not be subject to comparative review.

Section 21. Health Service Areas

Sec. 21. Counties assigned to each of the health service areas are as follows:

HSA		COUNTIES	
1	Livingston	Monroe	St. Clair
	Macomb	Oakland	Washtenaw
	Wayne		
2	Clinton	Hillsdale	Jackson
	Eaton	Ingham	Lenawee
3	Barry	Calhoun	St. Joseph
	Berrien	Cass	Van Buren
	Branch	Kalamazoo	
4	Allegan	Mason	Newaygo
	Ionia	Mecosta	Oceana
	Kent	Montcalm	Osceola
	Lake	Muskegon	Ottawa
5	Genesee	Lapeer	Shiawassee
6	Arenac	Huron	Roscommon
	Bay	Iosco	Saginaw
	Clare	Isabella	Sanilac
	Gladwin	Midland	Tuscola
	Gratiot	Ogemaw	
7	Alcona	Crawford	Missaukee
	Alpena	Emmet	Montmorency
	Antrim	Gd Traverse	Oscoda
	Benzie	Kalkaska	Otsego
	Charlevoix	Leelanau	Presque Isle
	Cheboygan	Manistee	Wexford
8	Alger	Gogebic	Mackinac
	Baraga	Houghton	Marquette
	Chippewa	Iron	Menominee
	Delta	Keweenaw	Ontonagon
	Dickinson	Luce	Schoolcraft

APPENDIX A

~~CON REVIEW STANDARDS~~ ~~FOR MRI SERVICES~~

Rural Michigan counties are as follows:

Alcona	~~Hillsdale~~	Oceana
Alger	Huron	Ogemaw
Antrim	Iosco	Ontonagon
Arenac	Iron	Osceola
Baraga	Lake	Oscoda
Charlevoix	Luce	Otsego
Cheboygan	Mackinac	Presque Isle
Clare	Manistee	Roscommon
Crawford	~~Mason~~	Sanilac
Emmet	~~Montcalm~~	Schoolcraft
Gladwin	Montmorency	Tuscola
Gogebic	NEWAYGO	

Micropolitan statistical area Michigan counties are as follows:

Allegan	HILLSDALE	MASON
Alpena	Houghton	Mecosta
Benzie	IONIA	Menominee
Branch	Isabella	~~Midland~~
Chippewa	Kalkaska	Missaukee
Delta	Keweenaw	St. Joseph
Dickinson	Leelanau	Shiawassee
Grand Traverse	Lenawee	Wexford
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	~~Ionia~~	MONTCALM~~Newaygo~~
Bay	Jackson	Muskegon
Berrien	Kalamazoo	Oakland
Calhoun	Kent	Ottawa
Cass	Lapeer	Saginaw
Clinton	Livingston	St. Clair
Eaton	Macomb	Van Buren
Genesee	MIDLAND	Washtenaw
Ingham	Monroe	Wayne

Source:

~~65~~ 75 F.R., p. ~~82238~~ 37245 (~~December 27~~JUNE 28, ~~2000~~2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED REVIEW (CON) STANDARDS FOR NEONATAL INTENSIVE CARE SERVICES/BEDS AND SPECIAL NEWBORN NURSING SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval of the initiation, replacement, relocation, expansion, or acquisition of neonatal intensive care services/beds and the delivery of neonatal intensive care services/beds under Part 222 of the Code. Further, these standards are requirements for the approval of the initiation or acquisition of special care nursery (SCN) services. Pursuant to Part 222 of the Code, neonatal intensive care services/beds and special newborn nursing services are covered clinical services. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) As used in these standards:

(a) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(b) "Code" means Act No. 368 of the Public Acts of 1978 as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(c) "Comparative group" means the applications which have been grouped for the same type of project in the same planning area and are being reviewed comparatively in accordance with the CON rules.

(d) "Department" means the Michigan Department of Community Health (MDCH).

(e) "Department inventory of beds" means the current list for each planning area maintained on a continuous basis by the Department of licensed hospital beds designated for NICU services and NICU beds with valid CON approval but not yet licensed or designated.

(f) "Existing NICU beds" means the total number of all of the following:

(i) licensed hospital beds designated for NICU services;

(ii) NICU beds with valid CON approval but not yet licensed or designated;

(ii) NICU beds under appeal from a final decision of the Department; and

(iii) proposed NICU beds that are part of an application for which a proposed decision has been issued, but is pending final Department decision.

(g) "Hospital" means a health facility licensed under Part 215 of the Code.

(h) "Infant" means an individual up to 1 year of age.

(i) "Licensed site" means in the case of a single site hospital, the location of the facility authorized by license and listed on that licensee's certificate of licensure; or in the case of a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility as authorized by license and listed on that licensee's certificate of licensure.

(j) "Live birth" means a birth for which a birth certificate for a live birth has been prepared and filed pursuant to Section 333.2821(2) of the Michigan Compiled Laws.

(k) "Maternal referral service" means having a consultative and patient referral service staffed by a physician(s), on the active medical staff, that is board certified, or eligible to be board certified, in maternal/fetal medicine.

(l) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396w-5.

(m) "Neonatal intensive care services" or "NICU services" means the provision of any of the following services:

(i) constant nursing care and continuous cardiopulmonary and other support services for severely ill infants;

(ii) care for neonates weighing less than 1,500 grams at birth, and/or less than 32 weeks gestation;

(iii) ventilatory support beyond that needed for immediate ventilatory stabilization;

(iv) surgery and post-operative care during the neonatal period;

(v) pharmacologic stabilization of heart rate and blood pressure; or

(vi) total parenteral nutrition.

(n) "Neonatal intensive care unit" or "NICU" means a specially designed, equipped, and staffed unit of a hospital which is both capable of providing neonatal intensive care services and is composed of licensed hospital beds designated as NICU. This term does not include unlicensed SCN beds.

(o) "Neonatal transport system" means a specialized transfer program for neonates by means of an ambulance licensed pursuant to Part 209 of the Code, being Section 333.20901 et seq.

(p) "Neonate" means an individual up to 28 days of age.

(q) "Perinatal care network," means the providers and facilities within a planning area that provide basic, specialty, and sub-specialty obstetric, pediatric and neonatal intensive care services.

(r) "Planning area" means the groups of counties shown in Appendix B.

(s) "Planning year" means the most recent continuous 12 month period for which birth data is available from the Vital Records and Health Data Development Section.

(t) "Qualifying project" means each application in a comparative group which has been reviewed individually and has been determined by the Department to have satisfied all of the requirements of Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards.

(u) "Relocation of the designation of beds for NICU services" means a change within the same planning area in the licensed site at which existing licensed hospital beds are designated for NICU services.

(v) "Special care nursery services" or “SCN services” means provisions of the services identified in subsections (i) through (v) for infants with problems that are expected to resolve rapidly and who would not be anticipated to need subspecialty services on an urgent basis. Referral to a higher level of care should occur for all infants who need pediatric surgical or medical subspecialty intervention. Infants receiving transitional care or being treated for developmental maturation may have formerly been treated in a neonatal intensive care unit in the same hospital or another hospital. For purposes of these standards, SCN services are special newborn nursing services.

(i) Care for low birth weight infants weighing 1,500grams or more and/or greater than or equal to 32 weeks gestation;

(ii) enteral tube feedings;

(iii) cardio-respiratory monitoring to document maturity of respiratory control or treatment of apnea;

(iv) extended care following an admission to a neonatal intensive care unit for an infant not requiring ventilatory support; or

(v) provide mechanical ventilation or continuous positive airway pressure or both for a brief duration (not to exceed 24 hours combined).

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Bed need methodology

Sec. 3. (1) The number of NICU beds needed in a planning area shall be determined by the following formula:

(a) Determine, using data obtained from the Vital Records and Health Data Development Section, the total number of live births which occurred in the planning year at all hospitals geographically located within the planning area.

(b) Determine, using data obtained from the Vital Records and Health Data Development Section, the percent of live births in each planning area and the state that were less than 1,500 grams. The result is the very low birth weight rate for each planning area and the state, respectively.

(c) Divide the very low birth weight rate for each planning area by the statewide very low birth weight rate. The result is the very low birth weight rate adjustment factor for each planning area.

(d) Multiply the very low birth weight rate adjustment factor for each planning area by 0.0045. The result is the bed need formula for each planning area adjusted for the very low birth weight rate.

(e) Multiply the total number of live births determined in subsection (1)(a) by the bed need formula for the applicable planning area adjusted for the very low birth weight adjustment factor as determined in subsection (1)(d).

(2) The result of subsection (1) is the number of NICU beds needed in the planning area for the planning year.

Section 4. Requirements to initiate NICU services

Sec. 4. Initiation of NICU services means the establishment of a NICU at a licensed site that has not had in the previous 12 months a licensed and designated NICU or does not have a valid CON to initiate a NICU. The relocation of the designation of beds for NICU services meeting the applicable requirements of Section 6 shall not be considered as the initiation of NICU services/beds.

(1) An applicant proposing to initiate NICU services by designating hospital beds as NICU beds shall demonstrate each of the following:

(a)There is an unmet bed need of at least 15 NICU beds based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year as a result of application of the methodology set forth in Section 3.

(b) Approval of the proposed NICU will not result in a surplus of NICU beds in the planning area based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year resulting from application of the methodology set forth in Section 3.

(c) A unit of at least 15 beds will be developed and operated.

(d) For each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the licensed site at which the NICU is proposed had either: (i) 2,000 or more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles (surface travel) from the nearest licensed site that operates or has valid CON approval to operate NICU services.

Section 5. Requirements to REPLACE NICU services

Sec. 5. Replacement of NICU beds means new physical plant space being developed through new construction or newly acquired space (purchase, lease or donation), to house existing licensed and designated NICU beds.

(1) An applicant proposing replacement beds shall not be required to be in compliance with the needed NICU bed supply determined pursuant to Section 3 if an applicant demonstrates all of the following:

(a) the project proposes to replace an equal or lesser number of beds designated by an applicant for NICU services at the licensed site operated by the same applicant at which the proposed replacement beds are currently located; and

(b) the proposed licensed site is in the same planning area as the existing licensed site and in the area set forth in Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, in which replacement beds in a hospital are not subject to comparative review.

Section 6. Requirements for approval to relocate NICU beds

Sec. 6. An applicant proposing to relocate the designation for NICU services shall demonstrate compliance with all of the following:

(1) The applicant is the licensed site to which the relocation of the designation of beds for NICU services is proposed.

(2) The applicant shall provide a signed written agreement that provides for the proposed increase, and concomitant decrease, in the number of beds designated for NICU services at the 2 licensed sites involved in the proposed relocation. A copy of the agreement shall be provided in the application.

(3) The existing licensed site from which the designation of beds for NICU services proposed to be relocated is currently licensed and designated for NICU services.

(4) The proposed project does not result in an increase in the number of beds designated for NICU services in the planning area unless the applicable requirements of Section 4 or 5 have also been met.

(5) The proposed project does not result in an increase in the number of licensed hospital beds at the applicant licensed site unless the applicable requirements of the CON Review Standards for Hospital Beds have also been met.

(6) The proposed project does not result in the operation of a NICU of less than 15 beds at the existing licensed site from which the designation of beds for NICU services are proposed to be relocated.

(7) If the applicant licensed site does not currently provide NICU services, an applicant shall demonstrate both of the following:

(a) the proposed project involves the establishment of a NICU of at least 15 beds; and

(b) for each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the applicant licensed site had either: (i) 2,000 or more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles from the nearest licensed site that operates or has valid CON approval to operate NICU services/beds. If the applicant licensed site has not been in operation for at least 3 years and the obstetrical unit at the applicant licensed site was established as the result of the consolidation and closure of 2 or more obstetrical units, the combined number of live births from the obstetrical units that were closed and relocated to the applicant licensed site may be used to evaluate compliance with this requirement for those years when the applicant licensed site was not in operation.

(8) If the applicant licensed site does not currently provide NICU services or obstetrical services, an applicant shall demonstrate both of the following:

(a) the proposed project involves the establishment of a NICU of at least 15 beds; and

(b) the applicant has a valid CON to establish an obstetrical unit at the licensed site at which the NICU is proposed. The obstetrical unit to be established shall be the result of the relocation of an existing obstetrical unit that for each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the obstetrical unit to be relocated had either: (i) 2,000 or more live births, if the obstetrical unit to be relocated is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the obstetrical unit to be relocated is located in a rural or micropolitan statistical area county and is located more than 100 miles from the nearest licensed site that operates or has valid CON approval to operate NICU services.

(9) The project results in a decrease in the number of licensed hospital beds that are designated for NICU services at the licensed site at which beds are currently designated for NICU services. The

decrease in the number of beds designated for NICU services shall be equal to or greater than the number of beds designated for NICU services proposed to be increased at the applicant's licensed site pursuant to the agreement required by this subsection. This subsection requires a decrease in the number of licensed hospital beds that are designated for NICU services, but does not require a decrease in the number of licensed hospital beds.

(10) Beds approved pursuant to Section 7(2) shall not be relocated pursuant to this section, unless the proposed project involves the relocation of all beds designated for NICU services at the applicant's licensed site.

Section 7. Requirements for approval to expand NICU services

Sec. 7. (1) An applicant proposing to expand NICU services at a licensed site by designating additional hospital beds as NICU beds in a planning area shall demonstrate that the proposed increase will not result in a surplus of NICU beds based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year resulting from application of the methodology set forth in Section 3.

(2) An applicant may apply and be approved for NICU beds in excess of the number determined as needed for the planning year in accordance with Section 3 if an applicant can demonstrate that it provides NICU services to patients transferred from another licensed and designated NICU. The maximum number of NICU beds that may be approved pursuant to this subsection shall be determined in accordance with the following:

(a) An applicant shall document the average annual number of patient days provided to neonates or infants transferred from another licensed and designated NICU, for the 2 most recent years for which verifiable data are available to the Department.

(b) The average annual number of patient days determined in accordance with subsection (a) shall be divided by 365 (or 366 for a leap year). The result is the average daily census (ADC) for NICU services provided to patients transferred from another licensed and designated NICU.

(c) Apply the ADC determined in accordance with subsection (b) in the following formula: ADC + 2.06 $\sqrt{ADC}$. The result is the maximum number of beds that may be approved pursuant to this subsection up to 5 beds at each licensed site.

Section 8. Requirements for approval to acquire a NICU service

Sec. 8. Acquisition of a NICU means obtaining possession and control of existing licensed hospital beds designated for NICU services by contract, ownership, lease or other comparable arrangement.

(1) An applicant proposing to acquire a NICU shall not be required to be in compliance with the needed NICU bed supply determined pursuant to Section 3 for the planning area in which the NICU subject to the proposed acquisition is located, if the applicant demonstrates that all of the following are met:

(a) the acquisition will not result in an increase in the number of hospital beds, or hospital beds designated for NICU services, at the licensed site to be acquired;

(b) the licensed site does not change as a result of the acquisition, unless the applicant meets Section 6; and,

(c) the project does not involve the initiation, expansion or replacement of a covered clinical service, a covered capital expenditure for other than the proposed acquisition or a change in bed capacity at the applicant facility, unless the applicant meets other applicable sections.

Section 9. Requirements to initiate, acquire, or replace SCN services

Sec. 9. An applicant proposing SCN services shall demonstrate each of the following, as applicable, by verifiable documentation:

(1) All applicants shall demonstrate the following:
(a) A board certified neonatologist serving as the program director.
(b) The hospital has the following capabilities and personnel continuously available and on-site:
(i) the ability to provide mechanical ventilation and/or continuous positive airway pressure for up to 24 hours;
(ii) portable x-ray equipment and blood gas analyzer;
(iii) pediatric physicians and/or neonatal nurse practitioners; and
(iv) respiratory therapists, radiology technicians, laboratory technicians and specialized nurses with experience caring for premature infants.

(2) Initiation of SCN services means the establishment of an SCN at a licensed site that has not had in the previous 12 months a designated SCN or does not have a valid CON to initiate an SCN.
(a) In addition to the requirements of Section 9(1), an applicant proposing to initiate an SCN service shall have a written consulting agreement with a hospital which has an existing, operational NICU. The agreement must specify that the existing service shall, for the first two years of operation of the new service, provide the following services to the applicant hospital:
(i) receive and make recommendations on the proposed design of SCN and support areas that may be required;
(ii) provide staff training recommendations for all personnel associated with the new proposed service;
(iii) assist in developing appropriate protocols for the care and transfer, if necessary, of premature infants;
(iv) provide recommendations on staffing needs for the proposed service; and
(v) work with the medical staff and governing body to design and implement a process that will annually measure, evaluate, and report to the medical staff and governing body the clinical outcomes of the new service, including:
(A) mortality rates;
(B) morbidity rates including intraventricular hemorrhage (grade 3 and 4), retinopathy of prematurity (stage 3 and 4), chronic lung disease (oxygen dependency at 36 weeks gestation), necrotizing enterocolitis, pneumothorax, neonatal depression (apgar score of less than 5 at five minutes); and
(C) infection rates.
(b) SCN services shall be provided in unlicensed SCN beds located within the hospital obstetrical department or NICU service. Unlicensed SCN beds are not included in the NICU bed need.

(3) Replacement of SCN services means new physical plant space being developed through new construction or newly acquired space (purchase, lease or donation), to house an existing SCN service.
(a) In addition to the requirements of Section 9(1), an applicant proposing a replacement SCN service shall demonstrate all of the following:
(i) The proposed project is part of an application to replace the entire hospital.
(ii) The applicant currently operates the SCN service at the current licensed site.
(iii) The proposed licensed site is in the same planning area as the existing licensed site.

(4) Acquisition of an SCN service means obtaining possession and control of an existing SCN service by contract, ownership, lease or other comparable arrangement.
(a) In addition to the requirements of Section 9(1), an applicant proposing to acquire an SCN service shall demonstrate all of the following:
(i) The proposed project is part of an application to acquire the entire hospital.

(ii) The licensed site does not change as a result of the acquisition, unless the applicant meets subsection 3.

Section 10. Additional requirements for applications included in comparative reviews.

Sec. 10. (1) Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and reviewed comparatively with other applications in accordance with the CON rules.

(2) Each application in a comparative review group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code, being Section 333.22225(1) of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards. If the Department determines that one or more of the competing applications satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1), and which have the highest number of points when the results of subsection (2) are totaled. If 2 or more qualifying projects are determined to have an identical number of points, the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1), which are proposed by an applicant that operates a NICU at the time an application is submitted to the Department. If 2 or more qualifying projects are determined to have an identical number of points and each operates a NICU at the time an application is submitted to the Department, the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1), in the order in which the applications were received by the Department, based on the submission date and time, as determined by the Department when submitted.

(a) A qualifying project will have points awarded based on the geographic proximity to NICU services, both operating and CON approved but not yet operational, in accordance with the following schedule:

Proximity	Points Awarded
Less than 50 Miles to NICU service	0
Between 50-99 miles to NICU service	1
100+ Miles to NICU service	2

(b) A qualifying project will have points awarded based on the number of very low birth weight infants delivered at the applicant hospital or the number of very low birth weight infants admitted or refused admission due to the lack of an available bed to an applicant's NICU, and the number of very low birth weight infants delivered at another hospital subsequent to the transfer of an expectant mother from an applicant hospital to a hospital with a NICU. The total number of points to be awarded shall be the number of qualifying projects. The number of points to be awarded to each qualifying project shall be calculated as follows:

(i) Each qualifying project shall document, for the 2 most recent years for which verifiable data are available, the number of very low birth weight infants delivered at an applicant hospital, or admitted to an applicant's NICU, if an applicant operates a NICU, the number of very low birth weight infants delivered to expectant mothers transferred from an applicant's hospital to a hospital with a NICU, and the number of very low birth weight infants referred to an applicant's NICU who were refused admission due to the lack of an available NICU bed and were subsequently admitted to another NICU.

(ii) Total the number of very low birth weight births and admissions documented in subdivision (i) for all qualifying projects.

(iii) Calculate the fraction (rounded to 3 decimal points) of very low birth weight births and admissions that each qualifying project's volume represents of the total calculated in subdivision (ii).

(iv) For each qualifying project, multiply the applicable fraction determined in subdivision (iii) by the total possible number of points.

(v) Each qualifying project shall be awarded the applicable number of points calculated in subdivision (iv).

(c) An applicant shall have 1 point awarded if it can be demonstrated that on the date an application is submitted to the Department, the licensed site at which NICU services/beds are proposed has on its active medical staff a physician(s) board certified, or eligible to be certified, in maternal/fetal medicine.

(d) A qualifying project will have points awarded based on the percentage of the hospital's indigent volume as set forth in the following table.

Hospital Indigent Volume	Points Awarded
0 - <6%	0.2
6 - <11%	0.4
11 - <16%	0.6
16 - <21%	0.8
21 - <26%	1.0
26 - <31%	1.2
31 - <36%	1.4
36 - <41%	1.6
41 - <46%	1.8
46% +	2.0

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total charges expressed as a percentage as determined by the Hospital and Health Plan Reimbursement Division pursuant to Section 7 of the Medical Provider manual. The indigent volume data being used for rates in effect at the time the application is deemed submitted will be used by the Department in determining the number of points awarded to each qualifying project.

(3) Submission of conflicting information in this section may result in a lower point reward. If an application contains conflicting information which could result in a different point value being awarded in this section, the Department will award points based on the lower point value that could be awarded from conflicting information. For example, if submitted information would result in 6 points being awarded, but other conflicting information would result in 12 points being awarded, then 6 points will be awarded. If the conflicting information does not affect the point value, the Department will award points accordingly. For example, if submitted information would result in 12 points being awarded and other conflicting information would also result in 12 points being awarded, then 12 points will be awarded.

Section 11. Requirements for Medicaid participation

Sec. 11. An applicant for NICU services and SCN services shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

Section 12. Project delivery requirements and terms of approval

Sec. 12. An applicant shall agree that, if approved, the NICU and SCN services shall be delivered in compliance with the following terms of approval:

(1) Compliance with these standards.

(2) Compliance with the following applicable quality assurance standards for NICU services:

(a) An applicant shall coordinate its services with other providers of obstetrical, perinatal, neonatal and pediatric care in its planning area, and other planning areas in the case of highly specialized services.

(b) An applicant shall develop and maintain a follow-up program for NICU graduates and other infants with complex problems. An applicant shall also develop linkages to a range of pediatric care for high-risk infants to ensure comprehensive and early intervention services.

(c) If an applicant operates a NICU that admits infants that are born at a hospital other than the applicant hospital, an applicant shall develop and maintain an outreach program that includes both case-finding and social support which is integrated into perinatal care networks, as appropriate.

(d) If an applicant operates a NICU that admits infants that are born at a hospital other than the applicant hospital, an applicant shall develop and maintain a neonatal transport system.

(e) An applicant shall coordinate and participate in professional education for perinatal and pediatric providers in the planning area.

(f) An applicant shall develop and implement a system for discharge planning.

(g) A board certified neonatologist shall serve as the director of neonatal services.

(h) An applicant shall make provisions for on-site physician consultation services in at least the following neonatal/pediatric specialties: cardiology, ophthalmology, surgery and neurosurgery.

(i) An applicant shall develop and maintain plans for the provision of highly specialized neonatal/pediatric services, such as cardiac surgery, cardiovascular surgery, neurology, hematology, orthopedics, urology, otolaryngology and genetics.

(j) An applicant shall develop and maintain plans for the provision of transferring infants discharged from its NICU to another hospital, as necessary for the care of an infant no longer requiring NICU services but unable to be discharged home.

(3) Compliance with the following applicable quality assurance standards for SCN services:

(a) An applicant shall coordinate its services with other providers of obstetrical, perinatal, neonatal and pediatric care in its planning area, and other planning areas in the case of highly specialized services.

(b) An applicant shall develop and implement a system for discharge planning.

(c) A board certified neonatologist shall serve as the SCN program director.

(d) The hospital continues to have the following capabilities and personnel continuously available and on-site:

(i) The ability to provide mechanical ventilation and/or continuous positive airway pressure for up to 24 hours;

(ii) portable x-ray equipment and blood gas analyzer;

(iii) pediatric physicians and/or neonatal nurse practitioners; and

(iv) respiratory therapists, radiology technicians, laboratory technicians and specialized nurses with experience caring for premature infants.

(4) Compliance with the following access to care requirements:

(a) The NICU and SCN services shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(b) The NICU and SCN services shall not deny NICU and SCN services to any individual based on ability to pay or source of payment.

(c) The NICU and SCN services shall provide NICU and SCN services to any individual based on clinical indications of need for the services.

(d) The NICU and SCN services shall maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

(e) Compliance with selective contracting requirements shall not be construed as a violation of this term.

(5) Compliance with the following monitoring and reporting requirements:

(a) The NICU and SCN services shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, operating schedules, through-put schedules, and demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to patients from all payor sources. The applicant shall provide the required data on a separate basis for each licensed site; in a format established by the Department; and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(i) The SCN services shall provide data for the percentage of transfers to a higher level of care, hours of life at the time of transfer to a higher level of care, admissions to the SCN at less than 32 weeks gestation, number of admissions requiring respiratory support greater than 24 hours in duration, number of admissions to SCN, and rates of morbidity including: intraventricular hemorrhage (grade 3 and 4), retinopathy of prematurity (stage 3 and 4), chronic lung disease (oxygen dependency at 36 weeks gestation), necrotizing enterocolitis, and pneumothorax.

(b) The NICU and SCN services shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.

(6) The agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant or its authorized agent.

Section 13. Department inventory of beds

Sec. 13. The Department shall maintain a listing of the Department inventory of beds for each planning area.

Section 14. Effect on prior CON review standards; comparative reviews

Sec. 14. (1) These CON review standards supercede and replace the CON Review Standards for Neonatal Intensive Care Services/Beds approved by the Commission on ~~June 10, 2010~~DECEMBER 12, 2013 and effective on ~~August 12, 2010~~MARCH 3, 2014.

(2) Projects reviewed under these standards shall be subject to comparative review except for:

(a) Replacement beds meeting the requirements of Section 22229(3) of the Code, being Section 333.22229(3) of the Michigan Compiled Laws;

(b) The designation of beds for NICU services being relocated pursuant to Section 6 of these standards; or

(c) Beds requested under Section 7(2).

(d) SCN services requested under Section 9.

APPENDIX A

~~CON REVIEW STANDARDS~~ FOR ~~NEONATAL INTENSIVE CARE SERVICES/BEDS~~

Rural Michigan counties are as follows:

Alcona	~~Hillsdale~~	Oceana
Alger	Huron	Ogemaw
Antrim	Iosco	Ontonagon
Arenac	Iron	Osceola
Baraga	Lake	Oscoda
Charlevoix	Luce	Otsego
Cheboygan	Mackinac	Presque Isle
Clare	Manistee	Roscommon
Crawford	~~Mason~~	Sanilac
Emmet	~~Montcalm~~	Schoolcraft
Gladwin	Montmorency	Tuscola
Gogebic	NEWAYGO	

Micropolitan statistical area Michigan counties are as follows:

Allegan	HILLSDALE	MASON
Alpena	Houghton	Mecosta
Benzie	IONIA	Menominee
Branch	Isabella	~~Midland~~
Chippewa	Kalkaska	Missaukee
Delta	Keweenaw	St. Joseph
Dickinson	Leelanau	Shiawassee
Grand Traverse	Lenawee	Wexford
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	~~Ionia~~	MONTCALM~~Newaygo~~
Bay	Jackson	Muskegon
Berrien	Kalamazoo	Oakland
Calhoun	Kent	Ottawa
Cass	Lapeer	Saginaw
Clinton	Livingston	St. Clair
Eaton	Macomb	Van Buren
Genesee	MIDLAND	Washtenaw
Ingham	Monroe	Wayne

Source:

~~65~~ 75 F.R., p. ~~82238~~ 37245 (~~December 27~~JUNE 28, ~~2000~~2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

APPENDIX B

The planning areas for neonatal intensive care services/beds are the geographic boundaries of the group of counties as follows:

Planning Areas	Counties
1	Livingston, Macomb, Monroe, Oakland, St. Clair, Washtenaw, Wayne
2	Clinton, Eaton, Hillsdale, Ingham, Jackson, Lenawee
3	Barry, Berrien, Branch, Calhoun, Cass, Kalamazoo, St. Joseph, Van Buren
4	Allegan, Ionia, Kent, Lake, Mason, Montcalm, Muskegon, Newaygo, Oceana, Ottawa
5	Genesee, Lapeer, Shiawassee
6	Arenac, Bay, Clare, Gladwin, Gratiot, Huron, Iosco, Isabella, Midland, Mecosta, Ogemaw, Osceola, Oscoda, Saginaw, Sanilac, Tuscola
7	Alcona, Alpena, Antrim, Benzie, Charlevoix, Cheboygan, Crawford, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, Montmorency, Otsego, Presque Isle, Roscommon, Wexford
8	Alger, Baraga, Chippewa, Delta, Dickinson, Gogebic, Houghton, Iron, Keweenaw, Luce, Mackinac, Marquette, Menominee, Ontonagon, Schoolcraft

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR SURGICAL SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. These standards are requirements for the approval of the initiation, replacement, expansion, or acquisition of a surgical service provided in a surgical facility and the delivery of these services under Part 222 of the Code. Surgical services provided in a freestanding surgical outpatient facility, an ambulatory surgery center certified under title XVIII, or a surgical department of a hospital licensed under Part 215 of the Code and offering inpatient or outpatient surgical services are covered clinical services . The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. For purposes of these standards:

(a) "Ambulatory surgical center" or "ASC" means any distinct entity certified by Medicare as an ASC under the provisions of Title 42, Part 416 that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization.

(b) "Burn care" means surgical services provided to burn patients in a licensed hospital site that has been verified as meeting the "Guidelines for Development and Operation of Burn Centers" issued by the American Burn Association in March 1988, or equivalent standards for a burn center.

(c) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(d) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(e) "Cystoscopy" means direct visual examination of the urinary tract with a cystoscope.

(f) "Cystoscopy case" means a single visit to an operating room during which one or more cystoscopic procedures are performed.

(g) “Dedicated endoscopy or cystoscopy operating room” means a room used exclusively for endoscopy or cystoscopy cases.

(h) "Department" means the Michigan Department of Community Health (MDCH).

(i) “Emergency Room” means a designated area in a licensed hospital and recognized by the Department as having met the staffing and equipment requirements for the treatment of emergency patients.

(j) "Endoscopy" means visual inspection of any portion of the body by means of an endoscope.

(k) "Endoscopy case" means a single visit to an operating room during which one or more endoscopic procedures are performed.

(l) "Existing surgical service" means a surgical facility that, on the date an application is submitted to the Department, is part of a licensed hospital site, a licensed freestanding surgical outpatient facility, or a certified ASC.

(m) "Freestanding surgical outpatient facility" or "FSOF" means a health facility licensed under Part 208 of the Code. It does not include a surgical outpatient facility owned and operated as a part of a licensed hospital site. A freestanding surgical outpatient facility is a health facility for purposes of Part 222 of the Code.

(n) "Hospital" means a health facility licensed under Part 215 of the Code.

(o) "Hours of use" means the actual time in hours, and parts thereof, an operating room is used to provide surgical services. It is the time from when a patient enters an operating room until that same patient leaves that same room. It excludes any pre- or post-operative room set-up or clean-up preparations, or any time a patient spends in pre- or post-operative areas including a recovery room.

(p) "Licensed hospital site" means either:

(i) in the case of a single site hospital, the location of the hospital authorized by license and listed on that licensee's certificate of licensure or

(ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient site as authorized by licensure.

(q) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to 1396v.

~~(r) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~

~~(s) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~

(~~t~~r) "Offer" means to perform surgical services.

(~~u~~s) "Operating room" or "OR" means a room in a surgical facility constructed and equipped to perform surgical cases and located on a sterile corridor. The term also includes a room constructed and equipped to perform surgical cases on a nonsterile corridor if the room is located in an FSOF or ASC that is used exclusively for endoscopy or cystoscopy cases. This term does not include procedure rooms.

(~~v~~t) "Operating suite," for purposes of these standards, means an area in a surgical facility that is dedicated to the provision of surgery. An operating suite includes operating rooms, pre- and post-operative patient areas, clean and soiled utility and linen areas, and other support areas associated with the provision of surgery.

(~~w~~u) "Outpatient surgery" means the provision of surgical services performed in a hospital, FSOF, or ASC, requiring anesthesia or a period of post-operative observation, or both, to patients whose admission to a hospital for an overnight stay is not anticipated as being medically necessary.

(~~x~~v) "Procedure room" means a room in a surgical facility constructed and equipped to perform surgical procedures and not located on a sterile corridor.

(~~y~~w) "Renovate an existing surgical service or one or more operating rooms" means a project that:

(i) involves the renovation, remodeling, or modernization of an operating suite of a hospital, FSOF, or ASC;

(ii) does not involve new construction;

(iii) does not involve a change in the physical location within the surgical facility at the same site; and

(iv) does not result in an increase in the number of operating rooms at an existing surgical facility.

Renovation of an existing surgical service or one or more operating rooms may involve a change in the number of square feet allocated to an operating suite. The renovation of an existing surgical service or one or more operating rooms shall not be considered the initiation, expansion, replacement, or acquisition of a surgical service or one or more operating rooms.

~~(z) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States Office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~

(~~aa~~x) "Sterile corridor" means an area of a surgical facility designated primarily for surgical cases and surgical support staff. Access to this corridor is controlled and the corridor is not used by the general public or personnel of the surgical facility whose primary work station is not in the operating suite(s) or whose primary work tasks do not require them to be in the operating suite(s) of a surgical facility. Examples of personnel who would normally use sterile corridors include physicians, surgeons, operating room nurses,

laboratory or radiology personnel, and central supply or housekeeping personnel. Other terms commonly used to represent "sterile" in describing access areas include "restricted," "controlled," "limited access," or "clean."

(~~bb~~y) "Surgical case" means a single visit to an operating room during which one or more surgical procedures are performed.

(ii) "Surgical facility" means either:

(i) a licensed FSOF;

(ii) a certified ASC; or

(iii) a licensed hospital site authorized to provide inpatient or outpatient surgery.

(jj) "Surgical service" means performing surgery in a surgical facility.

(~~cc~~z) "Trauma care," for purposes of these standards, means surgical services provided to a trauma patient in a licensed hospital site that has been verified as meeting the standards of the American College of Surgeons for a Level I or II trauma center, or equivalent standards.

(~~dd~~aa) "Verifiable data" means surgical data (cases and/or hours) from the most recent Annual Survey or more recent data that can be validated by the Department.

(2) Terms defined in the Code have the same meanings when used in these standards.

Section 3. Inventory of operating rooms used to perform surgical services; surgical cases, or hours of use; and evaluating compliance with minimum volume requirements

Sec. 3. (1) The Department shall use the number of operating rooms and verifiable data pursuant to subsection (2) to determine the number of surgical cases, hours of use, or both, as applicable, pursuant to subsection (3) for purposes of evaluating compliance with the actual and proposed volume requirements set forth in the applicable sections of these standards. Compliance with CON minimum volume requirements established by these standards shall be determined based on the average number of surgical cases, hours of use, or both, per operating room of the surgical service as permitted by these standards.

(2) The number of operating rooms for each type of surgical facility shall be determined as follows:

(a) In a licensed hospital site, all operating rooms in which surgery is or will be performed excluding:

(i) A delivery room(s) if that room is located in an area of a licensed hospital site designated primarily for obstetrical services.

(ii) An operating room that is or will be used exclusively for endoscopy or cystoscopy cases.

(iii) An operating room in which a fixed lithotripter is or will be located and utilized. A mobile lithotripter shall not be considered as an operating room.

(iv) An operating room that is or will be used, though not exclusively, to provide surgical services to patients requiring burn care or trauma care, as those terms are defined in these standards. No more than 0.5 burn care and 0.5 trauma care operating rooms shall be excluded pursuant to this subdivision, and precludes the use of the room in subsection (2)(a)(v).

(v) An operating room that is or will be used exclusively to provide surgical services to patients requiring burn care or trauma care, as those terms are defined in these standards. No more than 1 burn care and 1 trauma care operating room shall be excluded pursuant to this subdivision, and precludes the use of the room in subsection (2)(a)(iv).

(vi) A hybrid ORCCL shall have 0.5 excluded for each room meeting the requirements of section of these standards. A surgical facility will not be limited to the number of hybrid ORCCLS within a single licensed facility.

(b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all rooms in which endoscopy or cystoscopy cases are or will be performed.

(c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all operating rooms in which surgery is or will be performed, excluding any operating rooms used exclusively for endoscopy or cystoscopy cases.

(3) The number of surgical cases, or hours of use, shall be determined as follows:

(a) In a licensed hospital site, all surgical cases, or hours of use, performed in operating rooms, including surgical cases, or hours of use, performed in an operating room identified in subsection (2)(a)(iv), but excluding the surgical cases, or hours of use, performed in operating rooms identified in subsection (2)(a)(i), (ii), and (iii).

(b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all endoscopy or cystoscopy cases, or hours of use, performed in the operating rooms identified in subsection (2)(b).

(c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all surgical cases, or hours of use, performed in the operating rooms identified in subsection (2)(c). Cases, or hours of use, performed in any operating room used exclusively for endoscopy or cystoscopy cases, shall be excluded.

Section 4. Requirements to initiate a surgical service

Sec. 4. To initiate a surgical service means to begin operation of a surgical facility at a site that has not offered surgical services within the 12-month period immediately preceding the date an application is submitted to the Department. An applicant proposing to initiate a surgical service shall demonstrate the following, as applicable to the proposed project.

(1) Each proposed operating room shall perform an average of at least 1,128 surgical cases per year per operating room in the second 12 months of operation.

(2) Subsection (1) shall not apply if the proposed project involves the initiation of a surgical service with 1 or 2 operating rooms at a licensed hospital site located in a rural or micropolitan statistical area county that does not offer surgical services as of the date an application is submitted to the Department.

(3) An applicant shall demonstrate that it meets the requirements of Section 10(2) for the number of surgical cases projected under subsection (1).

Section 5. Requirements to replace a surgical service

Sec. 5. To replace a surgical service or one or more operating rooms, means the development of new space (whether through new construction, purchase, lease or similar arrangement) to house one or more operating rooms operated by an applicant at the same site as the operating room(s) to be replaced. This also includes designating an OR as a dedicated endoscopy or cystoscopy OR. The term also includes relocating an existing surgical facility or one or more operating rooms to a new geographic location of an existing surgical facility or one or more operating rooms to a different location currently offering surgical services. The term does not include the renovation of an existing surgical service or one or more operating rooms. An applicant requesting to replace an existing surgical service shall demonstrate each of the following, as applicable to the proposed project.

(1) An applicant proposing to replace shall demonstrate:

(a) All existing operating rooms in the existing surgical facility have performed an average of at least:

(i) 1,042 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room for which verifiable data is available to the Department, or

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.), or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(b) All operating rooms, existing and replaced, are projected to perform an average of at least:

(i) 1,042 surgical cases per year per operating room in the second twelve months of operation, and annually thereafter, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in the second twelve months of operation, and annually thereafter, or

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.), or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(2) An applicant proposing to replace one or more operating rooms at a licensed hospital and is located in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent federal decennial census shall demonstrate each of the following:

(a) The applicant has three, four, or five ORs at the licensed hospital.

(b) All existing operating rooms have performed an average of at least:

(i) 839 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,200 hours of use per year per operating room for which verifiable data is available to the Department.

(c) All operating rooms, existing and replaced, are projected to perform an average of at least:

(i) 839 surgical cases per year per operating room in the second twelve months of operation, and annually thereafter, or

(ii) 1,200 hours of use per year per operating room in the second twelve months of operation, and annually thereafter.

(3) Subsections (1) and (2) shall not apply if the proposed project involves replacing one or more operating rooms at the same licensed hospital site if the surgical facility is located in a rural or micropolitan statistical area county and has one or two operating rooms.

(4) Subsections (1) and (2) shall not apply to those hospitals licensed under Part 215 of PA 368 of 1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs at the surgical service has not increased as of March 31, 2003, and the location does not change.

(5) An applicant proposing to designate an OR as a dedicated endoscopy or cystoscopy OR shall submit notification to the Department on a form provided by the Department. An applicant under this subsection shall not be required to comply with subsections (1) and (2).

(6) An applicant proposing to relocate an existing surgical service or one or more operating rooms shall demonstrate each of the following, as applicable:

(a) The proposed new site is within a 10-mile radius of the site at which an existing surgical service is located if an existing surgical service is located in a metropolitan statistical area county, or a 20-mile radius if an existing surgical service is located in a rural or micropolitan statistical area county.

(b) All existing operating rooms in the surgical facility from which one or more ORs are proposed to be relocated have performed an average of at least:

(i) 1,042 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room for which verifiable data is available to the Department, or,

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.), or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(c) All operating rooms, existing and relocated, are projected to perform an average of at least:

(i) 1,042 surgical cases per year per operating room in the second twelve months of operation or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in the second twelve months of operation, and annually thereafter, or

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.) or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(7) Subsection (6) shall not apply if the proposed project involves relocating one or two operating rooms within a 20-mile radius if the surgical facility is located in a rural or micropolitan statistical area county.

(8) An applicant proposing to relocate one or more operating rooms from one licensed hospital site to another licensed hospital site and is located in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent federal decennial census shall demonstrate each of the following:

(a) The applicant has three, four, or five ORs at the licensed hospital.

(b) All existing operating rooms have performed an average of at least:

(i) 839 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,200 hours of use per year per operating room for which verifiable data is available to the Department.

(c) All operating rooms, existing and relocated, are projected to perform an average of at least:

(i) 839 surgical cases per year per operating room in the second twelve months of operation or

(ii) 1,200 hours of use per year per operating room in the second twelve months of operation,.

(9) An applicant shall demonstrate that it meets the requirements of Section 10(2) for the number of surgical cases, or hours of use, projected under subsection (1), (2), (6), and (8).

Section 6**. Requirements to expand an existing surgical service**

Sec. 6. To expand a surgical service means the addition of one or more operating rooms at an existing surgical service. This term also includes the change from a dedicated endoscopy or cystoscopy OR to a non-dedicated OR. An applicant proposing to add one or more operating rooms at an existing surgical service shall demonstrate each of the following as applicable, to the proposed project.

(1) An applicant shall demonstrate the following:

(a) All existing operating rooms in the existing surgical facility have performed an average of at least:

(i) 1,216 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,313 hours of use in a facility that performs only outpatient surgery per year per operating room for which verifiable data is available to the Department, or

(iii) a licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,750 plus the outpatient hours divided by 1,313. (For example: Using 438 inpatient hours and 985 outpatient hours would equate to 438/1,750 + 985/1,313 = 0.25 + 0.75 = 1.00 OR), or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,750 plus the outpatient cases divided by 1,216. (For example: Using 438 inpatient hours and 912 outpatient cases would equate to 438/1,750 + 912/1,216 = 0.25 + 0.75 = 1.00 OR.)

(b) All proposed operating rooms are projected to perform an average of at least:

(i) 1,042 surgical cases per year per operating room in the second twelve months of operation, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in the second twelve months of operation, or

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in the second twelve months of operation, and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to 375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00 OR.), or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room in the second twelve months of operation, and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to 375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00 OR.)

(2) An applicant proposing to add one or more operating rooms at a licensed hospital and is located in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent federal decennial census shall demonstrate each of the following:

(a) The applicant has two, three, or four ORs at the licensed hospital.

(b) All existing operating rooms have performed an average of at least:

(i) 979 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,400 hours of use per year per operating room for which verifiable data is available to the Department.

(c) All proposed operating rooms are projected to perform an average of at least:

(i) 839 surgical cases per year per operating room in the second twelve months of operation, or

(ii) 1,200 hours of use per year per operating room in the second twelve months of operation.

(3) Subsections (1) and (2) shall not apply if the proposed project involves adding a second operating room in a licensed hospital site located in a rural or micropolitan statistical area county that currently has only one operating room.

(4) An applicant shall demonstrate that it meets the requirements of Section 10(2) for the number of surgical cases, or hours of use, projected under subsections (1) and (2).

Section 7. Requirements to acquire an existing surgical service

Sec. 7. Acquisition of a surgical service means a project involving the issuance of a new license for a hospital or a freestanding surgical outpatient facility or a new certification as an ambulatory surgical center as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing surgical service. An applicant proposing to acquire an existing surgical service shall demonstrate each of the following, as applicable to the proposed project.

(1) An applicant agrees and assures to comply with all applicable project delivery requirements.

(2) For the first application proposing to acquire an existing surgical service, for which a final decision has not been issued, on or after January 27, 1996, the existing surgical service shall not be required to be in compliance with the applicable volume requirements set forth in these standards. The surgical service shall be operating at the applicable volume requirements in the second 12 months after the effective date of the acquisition.

(3) For any application proposing to acquire an existing surgical service except the first application, for which a final decision has not been issued, on or after January 27, 1996, the existing surgical service shall be required to be in compliance with the applicable volume requirements on the date the application is submitted to the Department.

(4) Subsection (3) shall not apply to those hospitals licensed under Part 215 of PA 368 of 1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs at the surgical service has not increased as of March 31, 2003, and the location does not change.

Section 8. Requirements for a Hybrid Operating Room/Cardiac Catheterization Laboratory (OR/CCL)

Sec. 8. A hybrid or/ccl means an operating room located on a sterile corridor and equipped with an angiography system permitting minimally invasive procedures of the heart and blood vessels with full anesthesia capabilities. An applicant proposing to add one or more hybrid OR/CCLS at an existing surgical service shall demonstrate each of the following:

(1) The applicant operates an open heart surgery service which is in full compliance with the current con review standards for open heart surgery services.

(2) If the hybrid OR/CCL(s) represents an increase in the number of licensed operating rooms at the facility, the applicant is in compliance with Section 6 of these standards.

(3) If the hybrid OR/CCL(s) represents conversion of an existing operating room(s), the applicant is in compliance with the provisions of Section 5, if applicable.

(4) The applicant meets the applicable requirements of the CON review standards for cardiac catheterization services.

(5) Each case performed in a hybrid OR/CCL shall be included either in the surgical volume or the therapeutic cardiac catheterization volume of the facility. No case shall be counted more than once.

Section 9. Requirements for Medicaid Participation

Sec. 9. An applicant shall provide Verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

Section 10. Project delivery requirements terms of approval for all applicants

Sec. 10. An applicant shall agree that, if approved, the surgical services shall be delivered in compliance with the following terms of approval:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(i) The designation of ORs as defined by the standards shall not be changed without prior notification to the Department.

(ii) Surgical facilities shall have established policies for the selection of patients and delineate procedures which may be performed in that particular facility.

(iii) Surgical facilities shall have provisions for handling all types of in-house emergencies, including cardiopulmonary resuscitation.

(iv) Surgical facilities performing outpatient surgery shall have policies which allow for hospitalization of patients when necessary. All surgeons who perform surgery within the facility shall have evidence of admitting privileges or of written arrangements with other physicians for patient admissions at a local hospital. The surgical facility shall have an established procedure, including a transfer agreement that provides for the immediate transfer of a patient requiring emergency care beyond the capabilities of the surgical facility to a hospital that is capable of providing the necessary inpatient services and is located within 30 minutes of the surgical facility. If no hospital is located within 30 minutes of the surgical facility, an applicant shall have a transfer agreement with the nearest hospital having such capability.

(v) An applicant shall have written policies and procedures regarding the administration of a surgical facility.

(vi) An applicant shall have written position descriptions which include minimum education, licensing, or certification requirements for all personnel employed at the surgical facility.

(vii) An applicant shall have a process for credentialing individuals authorized to perform surgery or provide anesthesia services at a surgical facility. An applicant's credentialing process shall insure that the selection and appointment of individuals to the staff of a surgical facility does not discriminate on the basis of licensure, registration, or professional education as doctors of medicine, osteopathic medicine and surgery, podiatric medicine and surgery, or dentistry.

(viii) An applicant shall provide laboratory, diagnostic imaging, pathology and pharmacy (including biologicals) services, either on-site or through contractual arrangements.

(ix) An applicant shall have written policies and procedures for advising patients of their rights.

(x) An applicant shall develop and maintain a system for the collection, storage, and use of patient records.

(xi) Surgical facilities shall have separate patient recovery and non-patient waiting areas.

(xii) Surgical facilities shall provide a functionally safe and sanitary environment for patients, personnel, and the public. Each facility shall incorporate a safety management program to maintain a physical environment free of hazards and to reduce the risk of human injury.

(B) For purposes of evaluating subsection (A), the Department shall consider it prima facie evidence as to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint Commission on the Accreditation of Healthcare Organizations, the American Osteopathic Hospital Association, or the Accreditation Association for Ambulatory Health Care, or certified by Medicare as an ambulatory surgical center.

(C) The operation of and referral of patients to the surgical facility shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

(3) Compliance with the following access to care requirements:

(a) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

(b) not deny surgical services to any individual based on ability to pay or source of payment;

(c) provide surgical services to any individual based on the clinical indications of need for the service.

(d) maintain information by payer and non-paying sources to indicate the volume of care from each source provided annually. Compliance with selective contracting requirements shall not be construed as a violation of this term.

(e) An applicant shall participate in Medicaid or in Medicaid managed care products at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter or attest that the applicant has been unable to contract with Medicaid managed care products at current Medicaid rates.

(4) Compliance with the following monitoring and reporting requirements:

(a) Existing operating rooms shall perform an average of at least:

(i) 1,042 surgical cases per year per operating room verifiable by the Department, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room verifiable by the Department, or

(iii) Be in compliance using the applicable weighted averages under Section 5.

(b) Existing operating rooms, located in a rural or micropolitan county, or within a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent Federal decennial census in a surgical service that has three, four, or five OR'S shall perform an average of at least:

(i) 839 surgical cases per year per operating room verifiable by the Department or

(ii) 1,200 hours of use per year per operating room verifiable by the Department.

(c) The applicant shall participate in a data collection System established and administered by the Department. The data may include, but is not limited to, hours of use of operating rooms, annual budget and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to patients from all payer sources. An applicant shall provide the required data on a separate basis for each licensed or certified site, in a format established by the department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(d) The surgical service shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.

(5) The agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant or its authorized agent.

Section 11. Documentation of projections

Sec. 11. (1) An applicant required to project volumes of service shall specify how the volume projections were developed and shall include only those surgical cases performed in an OR.

(a) The applicant shall include a description of the data source(s) used as well as an assessment of the accuracy of these data used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

(b) The Department shall subtract any previous commitment, pursuant to subsection 2(d).

(2) If a projected number of surgical cases, or hours of use, under subsection (1) includes surgical cases, or hours of use, performed at another existing surgical facility(s), an applicant shall demonstrate, with documentation satisfactory to the Department, that the utilization of the existing surgical facility(s) is in compliance with the volume requirements applicable to that facility, and will continue to be in compliance with the volume requirements (cases and/or hours) applicable to that facility subsequent to the initiation, expansion, or replacement of the surgical services proposed by an applicant. In demonstrating compliance with this subsection, an applicant shall provide each of the following:

(a) The name of each physician that performed surgical cases to be transferred to the applicant surgical facility.

(b) The number of surgical cases each physician, identified in subdivision (a), performed during the most recent 12-month period for which verifiable data is available.

(c) The location(s) at which the surgical cases to be transferred were performed, including evidence that the existing location and the proposed location are within 20 miles of each other.

(d) A written commitment from each physician, identified in subdivision (a), that he or she will perform at least the volume of surgical cases to be transferred to the applicant surgical facility for no less than 3 years subsequent to the initiation, expansion, or replacement of the surgical service proposed by an applicant.

(e) The number of surgical cases performed, at the existing surgical facility from which surgical cases will be transferred, during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable annual survey data is available.

(3) An applicant, other than an applicant proposing to initiate a surgical service, may utilize hours of use in documenting compliance with the applicable sections of these standards, if an applicant provides documentation, satisfactory to the Department, from the surgical facility from which the hours of use are being transferred.

Section 12. Effect on prior CON review standards; comparative reviews

Sec. 12. Proposed projects reviewed under these standards shall not be subject to comparative review. These CON review standards supercede and replace the CON Review Standards for Surgical Facilities approved by the CON Commission on ~~April 30, 2008~~DECEMBER 15, 2011 and effective on ~~June 20, 2008~~FEBRUARY 27, 2012.

APPENDIX A

CON REVIEW STANDARDS FOR SURGICAL SERVICES

Rural Michigan counties are as follows:

Alcona	~~Hillsdale~~	Oceana
Alger	Huron	Ogemaw
Antrim	Iosco	Ontonagon
Arenac	Iron	Osceola
Baraga	Lake	Oscoda
Charlevoix	Luce	Otsego
Cheboygan	Mackinac	Presque Isle
Clare	Manistee	Roscommon
Crawford	~~Mason~~	Sanilac
Emmet	~~Montcalm~~	Schoolcraft
Gladwin	Montmorency	Tuscola
Gogebic	NEWAYGO	

Micropolitan statistical area Michigan counties are as follows:

Allegan	HILLSDALE	MASON
Alpena	Houghton	Mecosta
Benzie	IONIA	Menominee
Branch	Isabella	~~Midland~~
Chippewa	Kalkaska	Missaukee
Delta	Keweenaw	St. Joseph
Dickinson	Leelanau	Shiawassee
Grand Traverse	Lenawee	Wexford
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	~~Ionia~~	MONTCALM~~Newaygo~~
Bay	Jackson	Muskegon
Berrien	Kalamazoo	Oakland
Calhoun	Kent	Ottawa
Cass	Lapeer	Saginaw
Clinton	Livingston	St. Clair
Eaton	Macomb	Van Buren
Genesee	MIDLAND	Washtenaw
Ingham	Monroe Wayne	

Source:

~~65~~ 75 F.R., p. ~~82238~~ 37245 (~~December 27~~JUNE 28, ~~2000~~2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR URINARY EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (UESWL) SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. These standards are requirements for approval to initiate, replace, expand, or acquire an UESWL service/unit under Part 222 of the Code. Urinary extracorporeal shock wave lithotripsy is a covered clinical service for purposes of Part 222 of the Code. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) "Central service coordinator" OR "CSC" means the organizational unit that has operational responsibility for a mobile UESWL service and its unit(s) and that is a legal entity authorized to do business in the state of Michigan.

(b) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(c) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(d) "Complicated stone disease treatment capability" means the expertise necessary to manage all patients during the treatment of kidney stone disease. This includes, but is not limited to:

(i) A urology service that provides skilled and experienced ureteroscopic stone removal procedures and

(ii) Experienced interventional radiologic support.

(e) "Department" means the Michigan Department of Community Health (MDCH).

(f) "Existing mobile UESWL unit" means a CON-approved and operational UESWL unit and transporting equipment operated by a central service coordinator that provides UESWL services to two or more host sites.

(g) "Existing UESWL service" means the utilization of a CON-approved and operational UESWL unit(s) at one site in the case of a fixed UESWL service or at each host site in the case of a mobile UESWL service.

(h) "Existing UESWL unit" means the utilization of a CON-approved and operational UESWL unit.

(i) "Hospital" means a health facility licensed under Part 215 of the Code.

(j) "Host site" means the site at which a mobile UESWL unit is authorized to provide UESWL services.

(k) "Licensed site" means either of the following:

(i) In the case of a single site health facility, the location of the facility authorized by license and listed on that licensee's Certificate of Licensure.

(ii) In the case of a health facility with multiple sites, the location of each separate and distinct health facility as authorized by license and listed on that licensee's Certificate of Licensure.

(l) "Michigan Inpatient Database" or "MIDB" means the database that is compiled by the Michigan Health and Hospital Association or successor organization. The database consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.

(m) "Mobile UESWL unit" means a UESWL unit and transporting equipment operated by a central service coordinator that provides UESWL services to two or more host sites.

(n) "Planning area" means the state of Michigan.

(o) “Region” means the geographic areas set forth in Appendix B.
(p) “Renewal of a lease” means extending the effective period of a lease for an existing UESWL unit that does not involve either the replacement/upgrade of a UESWL unit, as defined in Section 4, or a change in the parties to the lease.
(q) “Retreatment” means a UESWL procedure performed on the same side of the same patient within 6 months of a previous UESWL procedure performed at the same UESWL service. In the case of a mobile service, the term includes a retreatment performed at a different host site if the initial treatment was performed by the same service.
(r) "Ureteroscopic stone removal procedure" means a stone removal procedure conducted in the ureter by means of an endoscope that may or may not include laser technology.
(s) "Urinary extracorporeal shock wave lithotripsy" or "UESWL" means a procedure for the removal of kidney stones that involves focusing shock waves on kidney stones so that the stones are pulverized into sand-like particles, which then may be passed through the urinary tract.
(t) “UESWL service” means either the CON-approved utilization of a UESWL unit(s) at one site in the case of a fixed UESWL service or at each host site in the case of a mobile UESWL service.
(u) "UESWL unit" means the medical equipment that produces the shock waves for the UESWL procedure.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Requirements to initiate a urinary extracorporeal shock wave lithotripsy service

Sec. 3. Initiate a UESWL service means to begin operation of a UESWL unit, whether fixed or mobile, at a site that does not offer (or has not offered within the last consecutive 12-month period) approved UESWL services. The term does not include the acquisition or replacment of an existing UESWL service or the renewal of a lease.

(1) An applicant proposing to initiate a UESWL service shall demonstrate each of the following:
(a) The capability to provide complicated stone disease treatment on-site.
(b) At least 1,000 procedures are projected pursuant to the methodology set forth in Section 10(1).
(c) The proposed UESWL service shall be provided at a site that provides, or will provide, each of the following:
(i) On-call availability of an anesthesiologist and a surgeon.
(ii) On-site Advanced Cardiac Life Support (ACLS)-certified personnel and nursing personnel.
(iii) On-site IV supplies and materials for infusions and medications, blood and blood products, and pharmaceuticals, including vasopressor medications, antibiotics, and fluids and solutions.
(iv) On-site general anesthesia, EKG, cardiac monitoring, blood pressure, pulse oximeter, ventilator, general radiography and fluoroscopy, cystoscopy, and laboratory services.
(v) On-site crash cart.
(vi) On-site cardiac intensive care unit or a written transfer agreement with a hospital that has a cardiac intensive care unit.
(vii) On-site 23-hour holding unit.

Section 4. Requirements to replace an existing UESWL unit(s)

Sec. 4. Replace an existing UESWL unit means an equipment change of an existing UESWL unit, other than an upgrade, proposed by an applicant that results in that applicant operating the same number of UESWL units before and after the project completion. The term does not include an upgrade of an existing UESWL unit, changing a mobile UESWL unit to a fixed UESWL unit, or changing a fixed UESWL unit to a mobile UESWL unit. Replacement also means a change in the location of a fixed UESWL unit(s) from the existing site to a different site, OR a change in the geographic location of an existing fixed UESWL service and its unit(s) from an existing site to a different site.

(1) "Upgrade an existing UESWL unit" means any equipment change, other than a replacement, that involves a capital expenditure of $125,000 or less in any consecutive 24-month period.

(2) An applicant proposing to replace an existing UESWL unit(s) shall demonstrate the following:
(a) Each existing UESWL unit of the service proposing to replace a UESWL unit has averaged at least 1,000 UESWL procedures per unit during the most recent continuous 12-month period for which the Department has verifiable data.
(b) Each UESWL unit of the service proposing to replace a UESWL unit is projected to perform at least 1,000 UESWL procedures per unit per year pursuant to the methodology set forth in Section 10.

(3) An applicant proposing to replace a UESWL unit shall demonstrate one or more of the following:
(a) The existing equipment clearly poses a threat to the safety of the public.
(b) The proposed replacement UESWL unit offers technological improvements that enhance quality of care, increase efficiency, or reduce operating costs and patient charges.
(c) The existing equipment is fully depreciated according to generally accepted accounting principles.

(4) An applicant that demonstrates that it meets the requirements in this subsection shall not be required to demonstrate compliance with Section 4(2):
(a) The proposed project involves replacing 1 existing fixed UESWL unit with 1 mobile UESWL unit.
(b) The proposed mobile unit will serve at least 1 host site that is located in a region other than the region in which the fixed UESWL unit proposed to be replaced is located currently.
(c) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposed to operate when the results of the methodology in Section 10 are combined for the following, as applicable:
(i) All licensed hospital sites committing MIDB data pursuant to Section 11, as applicable, that are located in the region identified in subsection (c).
(ii) All sites that receive UESWL services from an existing UESWL service and propose to receive UESWL services from the proposed mobile unit and that are located in the region identified in subsection (c).
(d) A separate application from each host site is filed at the same time the application to replace a fixed unit is submitted to the Department.
(e) The proposed mobile UESWL unit is projected to perform at least 1,000 procedures annually pursuant to the methodology set forth in Section 10.

(5) An applicant proposing to relocate its existing UESWL service and its unit(s) shall demonstrate that the proposed project meets all of the following:
(a) The UESWL service and its unit(s) to be relocated is a fixed UESWL unit(s).
(b) The UESWL service to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.
(c) The site to which the UESWL service will be relocated meets the requirements of Section 3(1)(c).
(d) The proposed new site is in the state of Michigan and within a 25-mile radius of the existing site of the UESWL service to be relocated.
(e) The UESWL service and its unit(s) to be relocated performed an average of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data.
(f) The applicant agrees to operate the UESWL service and its unit(s) in accordance with all applicable project delivery requirements set forth in Section 9 of these standards.

(6) An applicant proposing to relocate a fixed UESWL unit(s) of an existing UESWL service shall demonstrate that the proposed project meets all of the following:
(a) The existing UESWL service from which the UESWL unit(s) is to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.
(b) The site to which the UESWL unit(s) will be relocated meets the requirements of Section 3(1)(c).
(c) The proposed new site is in the state of Michigan and within a 25-mile radius of the existing site of the fixed UESWL unit to be relocated.
(d) Each existing UESWL unit(s) at the service from which a unit is to be relocated performed at least an average of 1,000 procedures per fixed unit in the most recent 12-month period for which the Department has verifiable data.

(e) The applicant agrees to operate the UESWL unit(s) in accordance with all applicable project delivery requirements set forth in Section 9 of these Standards.

(f) For volume purposes, the new site shall remain associated with the existing UESWL service for a minimum of three years.

(7) Equipment that is replaced shall be removed from service and disposed of or rendered considerably inoperable on or before the date that the replacement equipment becomes operational.

Section 5. Requirements for approval to expand an existing UESWL service

Sec. 5. Expand an existing UESWL service means the addition of one UESWL unit at an existing UESWL service. An applicant proposing to expand an existing UESWL service, whether fixed or mobile, unless otherwise specified, shall demonstrate the following:

(1) All of the applicant's existing UESWL units, both fixed and mobile, at the same geographic location as the proposed additional UESWL unit, have performed an average of at least 1,800 procedures per UESWL unit during the most recent 12-month period for which the Department has verifiable data. In computing this average, the Department will divide the total number of UESWL procedures performed by the applicant's total number of UESWL units, including both operational and approved but not operational fixed and mobile UESWL units.

(2) The applicant shall project an average of at least 1,000 procedures for each existing and proposed fixed and mobile UESWL unit(s) as a result from the application of the methodology in Section 10 of these standards for the second 12-month period after initiation of operation of each additional UESWL unit whether fixed or mobile.

(3) An applicant proposing to expand an existing mobile UESWL service must provide a copy of the existing or revised contracts between the central service coordinator and each host site(s) that includes the same stipulations as specified in Section 7(1)(c).

Section 6. Requirements to acquire an existing UESWL service or an existing UESWL unit(s)

Sec. 6. Acquisition of an existing UESWL service or existing UESWL unit(s)" means obtaining possession or control of an existing fixed or mobile UESWL service or existing UESWL unit(s) by purchase, lease, donation, or other comparable arrangement.

(1) An applicant proposing to acquire an existing fixed or mobile UESWL service and its unit(s) shall demonstrate that a proposed project meets all of the following:

(a) For an application for the proposed first acquisition of an existing fixed or mobile UESWL service, for which a final decision has not been issued after May 2, 1998, an existing UESWL service to be acquired shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs. The UESWL service and its unit(s) shall be operating at the applicable volume requirements set forth in Section 9 of these standards in the second 12 months after the date the service and its unit(s) is acquired, and annually thereafter.

(b) For any application for proposed acquisition of an existing fixed or mobile UESWL service, except the first application approved pursuant to subsection (a), for which a final decision has not been issued after MAY 2, 1998, an applicant shall be required to demonstrate that the UESWL service and its unit(s) to be acquired performed an average of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data.

(2) An applicant proposing to acquire an existing fixed or mobile UESWL unit(S) of an existing UESWL service shall demonstrate that the proposed project meets all of the following:

(a) For any application for proposed acquisition of an existing fixed or mobile UESWL unit(s), an applicant shall be required to demonstrate that the UESWL unit(s) to be acquired performed an average

of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data.

(b) The requirements of Section 3(1)(c) have been met.

Section 7. Additional requirements for approval for mobile UESWL services

Sec. 7. (1) An applicant proposing to begin operation of a mobile UESWL service in Michigan shall demonstrate that it meets all of the following:

(a) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposing to operate when the results of the methodology in Section 10 are combined for the following, as applicable:

(i) All licensed hospital sites committing MIDB data pursuant to Section 11, as applicable, that are located in the region identified in subsection (b).

(ii) All sites that receive UESWL services from an existing UESWL unit and propose to receive UESWL services from the proposed mobile unit are located in the region(s) identified in subsection (b).

(b) The normal route schedule, the procedures for handling emergency situations, and copies of all potential contracts related to the mobile UESWL service and its unit(s) shall be included in the CON application submitted by the central service coordinator.

(2) The requirements of sections 3, 4, and subsection (1)(a) shall not apply to an applicant that proposes to add a Michigan site as a host site if the applicant demonstrates that the mobile UESWL service and its unit(s) operates predominantly outside of Michigan and all of the following requirements are met:

(a) The proposed host site is located in a rural or micropolitan statistical area county.

(b) All existing and approved Michigan UESWL service and its unit(s) locations (whether fixed or mobile) are in excess of 50 miles from the proposed host site and within a region currently served by a UESWL mobile service operating predominantly outside of Michigan.

(c) A separate CON application has been submitted by the CSC and each proposed host site.

(3) A central service coordinator proposing to add, or an applicant proposing to become, a host site on either an existing or a proposed mobile UESWL service shall demonstrate that it meets the requirements of Section 3(1)(C).

(4) A central service coordinator proposing to add, or an applicant proposing to become, a host site on an existing mobile UESWL service in a region not currently served by that service shall demonstrate that at least 100 UESWL procedures are projected in each region in which the existing mobile UESWL service is proposing to add a host site when the results of the methodology in Section 10 are combined for the following, as applicable:

(a) All licensed hospital sites committing MIDB data pursuant to Section 11, as applicable, are located in that region(s).

(b) All sites that receive UESWL services from an existing UESWL service and its unit(s) and propose to receive UESWL services from the proposed mobile service and its unit(s) are located in that region(s).

Section 8. Requirements for Medicaid participation

Sec. 8. An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of service if a CON is approved.

Section 9. Project delivery requirements terms of approval for all applicants

Sec 9. An applicant shall agree that, if approved, UESWL services, including all existing and approved UESWL units, shall be delivered in compliance with the following:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) The medical staff and governing body shall receive and review at least annual reports describing activities of the UESWL service, including complication rates, morbidity data, and retreatment rates.

(b) An applicant shall accept referrals for UESWL services from all appropriately licensed health care practitioners.

(c) An applicant shall develop and utilize a standing medical staff and governing body rule that provides for the medical and administrative control of the ordering and utilization of UESWL services.

(d) An applicant shall require that each urologist serving as a UESWL surgeon shall have completed an approved training program in the use of the lithotripter at an established facility with UESWL services.

(e) An applicant shall establish a process for credentialing urologists who are authorized to perform UESWL procedures at the applicant facility. This shall not be construed as a requirement to establish specific credentialing requirements for any particular hospital or UESWL site.

(f) A urologist who is not an active medical staff member of an applicant facility shall be eligible to apply for limited staff privileges to perform UESWL procedures. Upon request by the Department, an applicant shall provide documentation of its process that will allow a urologist who is not an active medical staff member to apply for medical staff privileges for the sole and limited purpose of performing UESWL procedures. In order to be granted staff privileges limited to UESWL procedures, a urologist shall demonstrate that he or she meets the same requirements, established pursuant to the provisions of subsection (e), that a urologist on an applicant facility's active medical staff must meet in order to perform UESWL procedures.

(g) An applicant shall provide UESWL program access to approved physician residency programs for teaching purposes.

(3) Compliance with the following access to care requirements:

(a) An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

(i) Not deny any UESWL services to any individual based on inability to pay or source of payment,

(ii) Provide all UESWL services to any individual based on clinical indications of need for the services, and

(iii) Maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

(b) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(c) The operation of and referral of patients to the UESWL service shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(4) Compliance with the following monitoring and reporting requirements:

(a) Each UESWL unit, whether fixed or mobile, shall perform at least an average of 1,000 procedures per unit per year in the second 12 months of operation and annually thereafter. The central service coordinator shall demonstrate that a mobile UESWL unit approved pursuant to these standards performed at least 100 procedures in each region that is served by the mobile unit. For purposes of this requirement, the number of UESWL procedures performed at all host sites in the same region shall be combined.

(b) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information; operating schedules; and demographic, diagnostic, morbidity and mortality information; primary diagnosis code; whether the procedure was a first or retreatment UESWL procedure; what other treatment already has occurred; outpatient or inpatient status; complications; and whether follow-up procedures (e.g., percutaneous nephrotomy) were required, as well as the volume of care provided to patients from all payor sources. An applicant shall provide the required data on a separate basis for each host site or licensed site in a format established by the Department and in a mutually-agreed-upon media. The Department may elect to verify the data through on-site review of appropriate records.

(c) The applicant shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.

(5) Compliance with the following mobile UESWL requirements, if applicable:

(a) The volume of UESWL procedures performed at each host site shall be reported to the Department by the central service coordinator.

(b) An applicant with an approved CON for a mobile UESWL service shall notify the Department and the local CON review agency, if any, at least 30 days prior to dropping an existing host site.

(c) Each mobile UESWL service shall establish and maintain an Operations Committee consisting of the central service coordinator's medical director and members representing each host site and the central service coordinator. This committee shall oversee the effective and efficient use of the UESWL unit, establish the normal route schedule, identify the process by which changes are to be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile UESWL service and its unit(s) on at least a quarterly basis.

(d) The central service coordinator shall arrange for emergency repair services to be available 24 hours each day for the mobile UESWL unit equipment and the vehicle transporting the equipment.

(e) If the host site will not be performing the lithotripsy procedures inside the facility, it must provide a properly prepared parking pad for the mobile UESWL unit of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host site also must provide the capability for maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host site to provide for immediate notification of emergency medical situations.

(f) A mobile UESWL service shall operate under a contractual agreement that includes the provision of UESWL services at each host site on a regularly scheduled basis.

(6) The agreements and assurances required by this Section shall be in the form of a certification agreed to by the applicant or its authorized agent.

Section 10. Methodology for projecting UESWL procedures

Sec. 10. (1) The methodology set forth in this subsection shall be used for projecting the number of UESWL procedures at a site or sites that do not provide UESWL services as of the date an application is submitted to the Department. In applying the methodology, actual inpatient discharge data, as specified in the most recent Michigan Inpatient Database available to the Department on the date an application is deemed complete shall be used for each licensed hospital site for which a signed data commitment form has been provided to the Department in accordance with the provisions of Section 11. In applying inpatient discharge data in the methodology, each inpatient record shall be used only once and the following steps shall be taken in sequence:

(a) The number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM codes 592.0, 592.1, or 592.9 (see Appendix D for ICD-10-CM Codes) shall be counted.

(b) The result of subsection (a) shall be multiplied by the factor specified in Appendix A for each licensed hospital site that is committing its inpatient discharge data to a CON application. If more than one licensed hospital site is committing inpatient discharge data in support of a CON application, the products from the application of the methodology for each licensed hospital site shall be summed.

(c) The result of subsection (b) is the total number of projected UESWL procedures for an application that is proposing to provide fixed or mobile UESWL services at a site, or sites in the case of a mobile service, that does not provide UESWL service, either fixed or mobile, as of the date an application is submitted to the Department.

(2) For a site or sites that provide UESWL services as of the date an application is submitted to the Department, the actual number of UESWL procedures performed at each site, during the most recent continuous 12-month period for which the Department has verifiable data, shall be the number used to project the number of UESWL procedures that will be performed at that site or sites.

(3) For a proposed UESWL unit, except for initiation, the results of subsections (1) and (2), as applicable, shall be summed and the result is the projected number of UESWL procedures for the proposed UESWL unit for purposes of the applicable sections of these standards.

(4) An applicant that is projecting UESWL procedures pursuant to subsection (1) shall provide access to verifiable hospital-specific data and documentation using a format prescribed by the Department.

Section 11. Requirements for MIDB data commitments

Sec. 11. (1) In order to use MIDB data in support of an application for UESWL services, an applicant shall demonstrate or agree to, as applicable, all of the following.

(a) A licensed hospital site whose MIDB data is used in support of a CON application for a UESWL service shall not use any of its MIDB data in support of any other application for a UESWL service for 5 years following the date the UESWL service to which the MIDB data are committed begins to operate. The licensed hospital site shall be required to commit 100% of its inpatient discharge data to a CON application.

(b) The licensed hospital site, or sites, committing MIDB data to a CON application has completed the departmental form(s) that agrees to or authorizes each of the following:

(i) The Michigan Health and Hospital Association may verify the MIDB data for the Department.

(ii) An applicant shall pay all charges associated with verifying the MIDB data.

(iii) The commitment of the MIDB data remains in effect for the period of time specified in subsection (1)(a).

(c) A licensed hospital site that is proposing to commit MIDB data to an application is admitting patients regularly as of the date the director makes the final decision on that application under Section 22231(9) of the Code, being Section 333.22231(9) of the Michigan Compiled Laws.

(2) The Department shall consider an MIDB data commitment in support of an application for a UESWL service from a licensed hospital site that meets all of the following:

(a) The licensed hospital site proposing to commit MIDB data to an application does not provide, or does not have a valid CON to provide, UESWL services, either fixed or mobile, as of the date an application is submitted to the Department.

(b) The licensed hospital site proposing to commit MIDB data is located in a region in which a proposed fixed UESWL service is proposed to be located or, in the case of a mobile unit, has at least one host site proposed in that region.

(c) The licensed hospital site meets the requirements of subsection (1), as applicable.

Section 12. Effect on prior planning policies; comparative reviews

Sec. 12. (1) These CON review standards supersede and replace the CON review standards for urinary extracorporeal shock wave lithotripsy (UESWL) services approved by the CON Commission on ~~December 11, 2007~~MARCH 18, 2014 and effective on ~~February 25, 2008~~JUNE 2, 2014.

(2) Projects reviewed under these standards shall not be subject to comparative review.

APPENDIX A

Factor For Calculating Projected UESWL Procedures

(1) Until changed by the Department, the factor to be used in Section 10(1)(b) used for calculating the projected number of UESWL procedures shall be 1.09.

(2) The Department may amend Appendix A by revising the factor in subsection (1) in accordance with the following steps:

(a) Steps for determining statewide UESWL adjustment factor:

(i) Determine the total statewide number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM codes 592.0, 592.1, or 592.9 (see Appendix D for ICD-10-CM Codes) for the most recent year for which Michigan Inpatient Database information is available to the Department.

(ii) Determine the total number of UESWL procedures performed in the state using the Department's Annual Hospital Questionnaire for the same year as the MIDB being used in subsection (i) above.

(iii) Divide the number of UESWL procedures determined in subsection (ii) above by the number of inpatient records determined in subsection (i) above.

(b) Steps for determining "urban/rural" adjustment factor:

(i) For each hospital, assign urban/rural status based on the 2000 census. "Metropolitan statistical area counties" will be assigned "urban" status, and "micropolitan statistical area" and "rural" counties will be assigned "rural" status.

(ii) Aggregate the records from step (a)(i) by zip code "urban/rural" status.

(iii) Identify the zip codes in which all records are either "urban" status or "rural" status. Aggregate the number of records and zip code populations separately by "urban/rural" status.

(iv) For zip codes having records in both "urban" and "rural" status, Calculate the proportion of records in "urban" and "rural" by dividing the respective number of records by the total number of records for that zip code. Multiply the population of each zip code by its respective "urban" and "rural" proportions.

(v) Aggregate the records and populations from step (b)(iv) separately by "urban/rural" status.

(vi) The sub-totals from step (v) will then be added to the sub-totals from step (iii) to produce totals for "urban" & "rural" separately. Calculate the "urban" and "rural" discharge rates per 10,000 (DRU and DRR, respectively) by dividing the total number of records by the total population for each status, then multiplying by 10,000.

(vii) Divide the urban discharge rate by the rural discharge rate (DRU/DRR) to calculate the "urban/rural" adjustment factor. Multiply the statewide adjustment factor identified in step (a)(iii) by the "urban/rural" adjustment factor. The result is the revised factor for calculating UESWL procedures.

(3) The Department shall notify the Commission when this revision is made and the effective date of the revision.

APPENDIX B

Counties assigned to each region are as follows:

Region	Counties			
1	Livingston	Monroe	Macomb	Oakland
	St. Clair	Washtenaw	Wayne	
2	Clinton	Eaton	Hillsdale	Ingham
	Jackson	Lenawee		
3	Barry	Berrien	Branch	Calhoun
	Cass	Kalamazoo	St. Joseph	Van Buren
4	Allegan	Ionia	Kent	Lake
	Mason	Mecosta	Montcalm	Muskegon
	Newaygo	Oceana	Osceola	Ottawa
5	Genesee	Lapeer	Shiawassee	
6	Arenac	Bay	Clare	Gladwin
	Gratiot	Huron	Iosco	Isabella
	Midland	Ogemaw	Roscommon	Saginaw
	Sanilac	Tuscola		
7	Alcona	Alpena	Antrim	Benzie
	Crawford	Charlevoix	Cheboygan	Emmet
	Gd. Traverse	Kalkaska	Leelanau	Manistee
	Missaukee	Montmorency	Oscoda	Otsego
	Presque Isle	Wexford		
8	Alger	Baraga	Chippewa	Delta
	Dickinson	Gogebic	Houghton	Iron
	Keweenaw	Luce	Mackinac	Marquette

APPENDIX C

~~CON REVIEW STANDARDS~~ FOR ~~UESWL~~ SERVICES

Rural Michigan counties are as follows:

Alcona	~~Hillsdale~~	Oceana
Alger	Huron	Ogemaw
Antrim	Iosco	Ontonagon
Arenac	Iron	Osceola
Baraga	Lake	Oscoda
Charlevoix	Luce	Otsego
Cheboygan	Mackinac	Presque Isle
Clare	Manistee	Roscommon
Crawford	~~Mason~~	Sanilac
Emmet	~~Montcalm~~	Schoolcraft
Gladwin	Montmorency	Tuscola
Gogebic	NEWAYGO	

Micropolitan statistical area Michigan counties are as follows:

Allegan	HILLSDALE	MASON
Alpena	Houghton	Mecosta
Benzie	IONIA	Menominee
Branch	Isabella	~~Midland~~
Chippewa	Kalkaska	Missaukee
Delta	Keweenaw	St. Joseph
Dickinson	Leelanau	Shiawassee
Grand Traverse	Lenawee	Wexford
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	~~Ionia~~	MONTCALM~~Newaygo~~
Bay	Jackson	Muskegon
Berrien	Kalamazoo	Oakland
Calhoun	Kent	Ottawa
Cass	Lapeer	Saginaw
Clinton	Livingston	St. Clair
Eaton	Macomb	Van Buren
Genesee	MIDLAND	Washtenaw
Ingham	Monroe	Wayne

Source:

~~65~~ 75 F.R., p. ~~82238~~ 37245 (~~December 27~~JUNE 28, ~~2000~~2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

APPENDIX D

ICD-9-CM TO ICD-10-CM CODE TRANSLATION

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
592.0	Calculus of Kidney	N20.0	Calculus of Kidney
		N20.2	Calculus of Kidney with Calculus of Ureter
592.1	Calculus of Ureter	N20.1	Calculus of Ureter
		N20.2	Calculus Of Kidney with Calculus of Ureter
592.9	Urinary Calculus	N20.9	Urinary Calculus, Unspecified
		N22	Calculus of Urinary Tract in Diseases Classified Elsewhere

"ICD-9-CM Code" means the disease codes and nomenclature found in the International Classification of Diseases - 9th Revision - Clinical Modification, prepared by the Commission on Professional and Hospital Activities for the U.S. National Center for Health Statistics.

"ICD-10-CM Code" means the disease codes and nomenclature found in the International Classification Of Diseases - 10th Revision - Clinical Modification, National Center for Health Statistics.

CERTIFICATE OF NEED

2nd Quarter Compliance Report to the CON Commission

October 1, 2013 through September 30, 2014 (FY 2014)

This report is to update the Commission on Department activities to monitor compliance of all Certificates of Need recipients as required by Section 22247 of the Public Health Code.

MCL 333.22247

(1) The department shall monitor compliance with all certificates of need issued under this part and shall investigate allegations of noncompliance with a certificate of need or this part.

(2) If the department determines that the recipient of a certificate of need under this part is not in compliance with the terms of the certificate of need or that a person is in violation of this part or the rules promulgated under this part, the department shall do 1 or more of the following:

(a) Revoke or suspend the certificate of need.

(b) Impose a civil fine of not more than the amount of the billings for the services provided in violation of this part.

(c) Take any action authorized under this article for a violation of this article or a rule promulgated under this article, including, but not limited to, issuance of a compliance order under section 20162(5), whether or not the person is licensed under this article.

(d) Request enforcement action under section 22253.

(e) Take any other enforcement action authorized by this code.

(f) Publicize or report the violation or enforcement action, or both, to any person.

(g) Take any other action as determined appropriate by the department.

(3) A person shall not charge to, or collect from, another person or otherwise recover costs for services provided or for equipment or facilities that are acquired in violation of this part. If a person has violated this subsection, in addition to the sanctions provided under subsection (2), the person shall, upon request of the person from whom the charges were collected, refund those charges, either directly or through a credit on a subsequent bill.

Activity Report

Follow Up: In accordance with Administrative Rules 325.9403 and 325.9417, the Department tracks approved Certificates of Need to determine if proposed projects have been implemented in accordance with Part 222. By rule, applicants are required to either implement a project within one year of approval or execute an enforceable contract to purchase the covered equipment or start construction, as applicable. In addition, an applicant must install the equipment or start construction within two years of approval.

Activity	2nd Quarter	Year-to-Date
Approved projects requiring 1-year follow up	83	170
Approved projects contacted on or before anniversary date	46	104
Approved projects completed on or before 1-year follow up	55%	
CON approvals expired	14	41
Total follow up correspondence sent	258	460
Total approved projects still ongoing	371	

Compliance: In accordance with Section 22247 and Rule 9419, the Department performs compliance checks on approved and operational Certificates of Need to determine if projects have been implemented, or if other applicable requirements have been met, in accordance with Part 222 of the Code.

The Department has taken the following actions:

- After a statewide review of the Open Heart Surgery data based on the 2010 Annual Survey, the Department opened 6 compliance investigations of Open Heart Surgery programs not meeting the approved volume requirement. The Department has completed collection of information and investigation of the same. The Department is in the process of determining compliance remedies, drafting compliance orders, and arranging meetings with these providers to resolve these investigations.

- After a statewide review of the Psychiatric Beds and Services data based on the 2010 Annual Survey, the Department opened 14 compliance investigations of adult and child/adolescent psychiatric programs not meeting the approved occupancy rates. The Department has completed collection of information and investigation of the same. The Department has closed 4 investigations based on more recent data and updated information. The Department has conducted meetings with the remaining 10 psychiatric hospitals (10 adult programs and 1 child/adolescent program) and has determined proposed compliance actions. The Department has sent draft settlement agreements to 9 programs to resolve these investigations and in the process of finalizing these agreements. Additionally, the Department reviewed the 2012 Psychiatric Beds and Services data based on the 2012 Annual Survey and is in the process of opening 2 additional compliance investigations.

- Randall N. Ruff, DDS – The Department issued a determination of non-compliance for the freestanding facility for providing dental CT services at a site that did not receive CON approval. The facility paid a civil fine of $600 (maximum amount billed and allowable by Statute) and was required to notify all third party payers. A corrective CON application was filed for this dental CT scanner service.

- Community Health Center of Branch County – This Hospital entered into a renewal of lease for their fixed MRI unit without CON approval. Hospital was required to file a corrective CON and paid a civil fine of $5,500.

Source: Certificate of Need Evaluation Section, Michigan Department of Community Health.

CERTIFICATE OF NEED

2nd Quarter Program Activity Report to the CON Commission

October 1, 2013 through September 30, 2014 (FY 2014)

This quarterly report is designed to assist the CON Commission in monitoring and assessing the operations and effectiveness of the CON Program Section in accordance with Section 22215(1)(e) of the Public Health Code, 1978 PA 368.

Measures

Administrative Rule R325.9201 requires the Department to process a Letter of Intent within 15 days upon receipt of a Letter of Intent.

Activity	2nd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	81	N/A	149	N/A
Letters of Intent Processed within 15 days	81	100%	148	99%
Letters of Intent Processed Online	81	100%	149	100%

Administrative Rule R325.9201 requires the Department to request additional information from an applicant within 15 days upon receipt of an application, if additional information is needed.

Activity	2nd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	50	N/A	116	N/A
Applications Processed within 15 Days	50	100%	116	100%
Applications Incomplete/More Information Needed	37	74%	81	70%
Applications Filed Online*	45	100%	104	100%
Application Fees Received Online*	13	29%	28	27%

* Number/percent is for only those applications eligible to be filed online, potential comparative and comparative applications are not eligible to be filed online, and emergency applications have no fee.

Administrative rules R325.9206 and R325.9207 require the Department to issue a proposed decision for completed applications within 45 days for nonsubstantive, 120 days for substantive, and 150 days for comparative reviews.

Activity	2nd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	55	100%	76	100%
Substantive Applications	26	100%	65	100%
Comparative Applications	4	100%	4	100%

Note: Data in this table may not total/correlate with application received table because receive and processed dates may carry over into next month/next quarter.

Measures – continued

Administrative Rule R325.9227 requires the Department to determine if an emergency application will be reviewed pursuant to Section 22235 of the Public Health Code within 10 working days upon receipt of the emergency application request.

Activity	2nd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Emergency Applications Received	0	N/A	0	N/A
Decisions Issued within 10 workings Days	0	N/A	0	N/A

Administrative Rule R325.9413 requires the Department to process amendment requests within the same review period as the original application.

Activity	2nd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	17	100%	30	100%

Section 22231(10) of the Public Health Code requires the Department to issue a refund of the application fee, upon written request, if the Director exceeds the time set forth in this section for a final decision for other than good cause as determined by the Commission.

Activity	2nd Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	2nd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	44	N/A	70	N/A
FOIA Requests Processed on Time	40	91%	66	94%
Number of Applications Viewed Onsite	0	N/A	0	N/A

FOIA – Freedom of Information Act.

Source: Certificate of Need Evaluation Section, Michigan Department of Community Health.

CERTIFICATE OF NEED LEGAL ACTION

(05.29.14)

Case Name	Date Opened	Case Description	Status
Medilodge of Oxford, et al v MDCH, et al Michigan Supreme Court No. 148212*Oakland – Compare Group #95-0217* Includes: *Medilodge of Oxford – CON App # 11-0045* *Medilodge of Clarkston – CON App # 11-0043* *Medilodge of Square Lk – CON App # 11-0041* *Regency on the Lk – CON App # 11-0033* *Manor of Farm. Hills – CON App # 11-0024* *Bloomfield Orchard – CON App # 11-0028* *Sen. Com. Of Auburn Hills – CON App # 11-0023* *Sen. Com. Of Prov. Pk. – CON App # 11-0022*	04/02/13	Application for Leave to Appeal the Circuit Court's 3/12/13 order affirming the Department's decision and dismissing the appeal.	On November 1, 2013 the Court of Appeals issued its Order denying the application for lack of merit. On December 9, 2013, the Medilodge entities filed an application for leave to appeal to the Michigan Supreme Court. On May 27, 2014 the Supreme Court denied Medilodge's Application for Leave to Appeal. This case is closed and the Department's denial is affirmed.

CERTIFICATE OF NEED LEGAL ACTION

(05.29.14)

Case Name	Date Opened	Case Description	Status
Pontiac Osteopathic Hospital dba McLaren Oakland Oakland County Circuit Court Includes: CON App # 12-0024 and 12-0025	6/20/13	Appeal of the MDCH Director's final decision.	On December 20, 2013, the Oakland County Circuit Court affirmed the Department's denial of McLaren's application for CON. On January 13, 2014, McLaren filed an Application for Leave to Appeal in the Court of Appeals. Both parties have filed briefs and we are waiting a decision.

CON Legal Action; report 03.12.14

Note: New or revised standards may include the provision that make the standard applicable, as of its effective date, to all CON applications for which a final decision has not been issued.

Attachment P

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2013												2014											
	J*	F	M*	A	M	J*	J	A	S*	O	N	D*	J*	F	M*	A	M	J*	J	A	S*	O	N	D*
Bone Marrow Transplantation (BMT) Services													• D	•	• R —	• P	•	• ▲F						
Cardiac Catheterization Services**									•	• PC	•	• R — 1	• R P A	• S	• ▲F S	• S	• S	▮	▮	▮	▮	▮	▮	▮
Computed Tomography (CT) Scanner Services	•R	•	•	•	•	•	•	•	•	•	•	• R —	• P	•	• ▲F			• R —	• P	•	• ▲F			
Hospital Beds									•	• PC	•	• R — 1	• R P A	•	• ▲F R	•	•	• R —	• P	•	• ▲F			
Magnetic Resonance Imaging (MRI) Services																		• R —	• P	•	• ▲F			
Megavoltage Radiation Therapy (MRT) Services/Units**										• PC	•	•	• R A	• S	• S	• S	• S	▮	▮	▮	▮	▮	▮	▮
Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services																		• R —	• P	•	• ▲F			
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups**	•R	•	•S	•S	•S	•S	•	•	•	•	•	•	•	•	•	•	•	R —	P	•	F▲			
Positron Emission Tomography (PET) Scanner Services										• PC	•	• R — 1	• R P A	•	• ▲F	•	•	•	•	•	•	•	•	R —
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	•R	•	•	•	•	•	•	•	• R	•	•	• R — 1	• P	•	• ▲F			• R —	• P	•	• ▲F			
New Medical Technology Standing Committee	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M
Commission & Department Responsibilities			M			M			M			M	M			M			M			M		
2-year Report to Joint Legislative Committee (JLC) – 1/1/15																								R

KEY

— - Receipt of proposed standards/documents, proposed Commission action
* - Commission meeting
▮ - Staff work/Standard advisory committee meetings
▲ - Consider Public/Legislative comment
** - Current in-process standard advisory committee or Informal Workgroup
• Staff work/Informal Workgroup/Commission Liaison Work/Standing Committee Work
1 ICD-10 Translation

A - Commission Action
C - Consider proposed action to delete service from list of covered clinical services requiring CON approval
D - Discussion
F - Final Commission action, Transmittal to Governor/Legislature for 45-day review period
M - Monitor service or new technology for changes
P - Commission public hearing/Legislative comment period
PC - Public Comment Period for initial comments on review standards for review in the upcoming year
R - Receipt of report
S - Solicit nominations for standard advisory committee or standing committee membership

For Approval June 12, 2014

Updated June 3, 2014

The CON Commission may revise this work plan at each meeting. For information about the CON Commission work plan or how to be notified of CON Commission meetings, contact the Michigan Department of Community Health, Office of Health Policy and Innovation, Health Planning and Access to Care Section, 7th Floor Capitol View Bldg., 201 Townsend St., Lansing, MI 48913, 517-335-6708, www.michigan.gov/con.

SCHEDULE FOR UPDATING CERTIFICATE OF NEED (CON) STANDARDS EVERY THREE YEARS*

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	June 2, 2014	2016
Bone Marrow Transplantation Services	March 22, 2013	2015
Cardiac Catheterization Services	June 2, 2014	2017
Computed Tomography (CT) Scanner Services	June 2, 2014	2016
Heart/Lung and Liver Transplantation Services	September 28, 2012	2015
Hospital Beds	June 2, 2014	2017
Magnetic Resonance Imaging (MRI) Services	September 18, 2013	2015
Megavoltage Radiation Therapy (MRT) Services/Units	May 24, 2013	2017
Neonatal Intensive Care Services/Beds (NICU)	March 3, 2014	2016
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	March 11, 2011	2016
Open Heart Surgery Services	June 2, 2014	2017
Positron Emission Tomography (PET) Scanner Services	June 2, 2014	2017
Psychiatric Beds and Services	March 22, 2013	2015
Surgical Services	February 27, 2012	2017
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	June 2, 2014	2016

*Pursuant to MCL 333.22215 (1)(m): "In addition to subdivision (b), review and, if necessary, revise each set of certificate of need review standards at least every 3 years."

**A Public Comment Period will be held in October prior to the review year to determine what, if any, changes need to be made for each standard scheduled for review. If it is determined that changes are necessary, then the standards can be deferred to a standard advisory committee (SAC), workgroup, or the Department for further review and recommendation to the CON Commission. If no changes are determined, then the standards are scheduled for review in another three years.

Note: Pancreas Transplantation services are no longer subject to and no longer require CON approval effective September 28, 2012.