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

Tuesday March 18, 2014

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

FINAL MINUTES

I. Call to Order & Introductions

Vice-Chairperson Keshishian called the meeting to order @ 9:34 a.m., and introduced Elizabeth Hertel as the new Director of Health Policy and Innovation at the Michigan Department of Community Health.

A. Members Present:

Gail J. Clarkson, RN
Kathleen Cowling, DO
Marc Keshishian, MD, Vice-Chairperson
Denise Brooks-Williams
Charles Gayney
Robert Hughes
Jessica Kochin
Suresh Mukherji, MD
Luis Tomatis, MD

B. Members Absent:

James B. Falahee, Jr., JD, Chairperson
Gay L. Landstrom, RN

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Community Health Staff Present:

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

II. Review of Agenda

Motion by Commissioner Gayney, seconded by Commissioner Mukherji, to approve the agenda as amended by the Chairperson – the Commission will accept public comment on items VIII – XI all at one time. Motion Carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of January 28, 2014

Motion by Commissioner Tomatis, seconded by Commissioner Clarkson, to approve the minutes of January 28, 2014 as presented. Motion Carried.

V. Air Ambulance (AA) Services – January 22, 2014 Public Comment Period Summary & Report

Ms. Rogers gave a brief overview of the public hearing summary (see Attachment A).

A. Public comment

None.

B. Commission Discussion

None.

C. Commission Final Action

Motion by Commissioner Clarkson, seconded by Commissioner Brooks-Williams, to approve the language (see Attachment B) as presented, and move it forward for the 45-day review period to the Joint Legislative Committee (JLC) and the governor. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

VI. Computed Tomography (CT) Services – January 22, 2014 Public Comment Summary & Report

Ms. Rogers gave a brief overview of the public hearing summary (see Attachment C).

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Final Action

Motion by Commissioner Cowling, seconded by Commissioner Tomatis, to approve the language (see Attachment D) as presented, and move it forward for the 45-day review period to the JLC and the governor. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

VII. Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units – January 22, 2014 Public Hearing Summary & Report

Ms. Rogers gave a brief overview of the public hearing summary (see Attachment E).

A. Public Comment

Dr. Robert Bates, Greater Michigan Lithotripsy
Dr. Thomas Mertz, Greater Michigan Lithotripsy
Melissa Cupp, Wiener Associates
Meg Tipton, Spectrum Health

B. Commission Discussion

Discussion followed.

C. Commission Final Action

Motion by Commissioner Gayney, seconded by Commissioner Mukherji, to approve the language (see Attachment F) as presented, and move it forward for the 45-day review period to the JLC and the governor. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

VIII. – XI. Cardiac Catheterization (CC) Services, Hospital Beds, Open Heart Surgery (OHS) Services and Positron Emission Tomography (PET) Scanner Services – January 22, 2014 Public Hearing Summary & Report

Ms. Rogers gave a brief overview of the public hearing summary (see Attachment G).

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Final Action

Motion by Commissioner Tomatis, seconded by Commissioner Hughes, to approve the language (see Attachment H) for CC Services as presented, and move it forward for the 45-day review period to the JLC and the governor. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

Motion by Commissioner Clarkson, seconded by Commissioner Gayney, to approve the language (see Attachment I) for Hospital Beds as presented, and move it forward for the 45-day review period to the JLC and the governor. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

Motion by Commissioner Cowling, seconded by Commissioner Tomatis, to approve the language (see Attachment J) for OHS Services as presented, and move it forward for the 45-day review period to the JLC and the governor. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

Motion by Commissioner Brooks-Williams seconded by Commissioner Mukherji, to approve the language (see Attachment K) for PET Scanner Services as presented, and move it forward for the 45-day review period to the JLC and the governor. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

XII. Bone Marrow Transplantation (BMT) Services – Department Report

Ms. Rogers gave a brief overview.

A. Public Comment

Carol Christner, Karmanos Cancer Center

B. Commission Discussion

Discussion followed.

C. Commission Proposed Action

Motion by Commissioner Gayney, seconded by Commissioner Tomatis, to approve the language (see Attachment L) as presented,

and move it forward for Public Hearing and to the JLC. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

XIII. Nursing Home and Hospital Long – Term Care Unit (HLTCU) Beds Workgroup Update (Written Report – see Attachment M)

XIV. Legislative Report

Mr. Blakeney gave a brief legislative update.

XV. Administrative Update

A. Planning & Access to care Section Update

Ms. Nagel gave a verbal update on the Cardiac Catheterization (CC) and Megavoltage Radiation Therapy (MRT) Standard Advisory Committees (SAC) nominations.

B. CON Evaluation Section Update

Ms. Bhattacharya gave a brief overview of the compliance report and quarterly performance measurements.

1. Compliance Report (Written Report – see Attachment N & Compliance Update).
2. Quarterly Performance Measures (Written Report – see Attachment O).

XVI. Legal Activity Report

Mr. Potchen gave a brief overview of the legal activity report (see Attachment P).

XVII. Future Meeting dates – June 12, 2014, September 25, 2014, & December 11, 2014

XVIII. Public Comment

Dennis McCafferty, Economic Alliance for Michigan (EAM)

XIX. Review of Commission Work Plan

Ms. Rogers gave a brief overview of the upcoming work plan (see Attachment Q).

A. Commission Discussion

None.

B. Commission Action

Motion by Commissioner Cowling, seconded by Commissioner Clarkson, to adopt the work plan. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

XX. Election of Officers

Motion by Commissioner Mukherji, seconded by Commissioner Cowling, to nominate and elect Vice-Chairperson Keshishian as Chairperson of the Commission. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

Motion by Commissioner Cowling, seconded by Commissioner Clarkson, to nominate and elect Commissioner Mukherji as Vice-Chairperson of the Commission. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

XXI. Adjournment

Motion by Commissioner Mukherji, seconded by Commissioner Cowling, to adjourn the meeting at 10:36 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: February 20, 2014

TO: Brenda Rogers

FROM: Natalie Kellogg

RE: Summary of Public Hearing Comments on Air Ambulance (AA) Services Standards

---

Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the AA Standards at its December 12, 2013 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed AA Standards on January 22, 2014. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was not received from any organizations.

Recommendations

The Department recommends that the Commission take final action to approve the language as presented at the December 12, 2013 meeting.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR AIR AMBULANCE 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 approval OF THE INITIATION, REPLACEMENT, EXPANSION, OR ACQUISITION OF AIR AMBULANCE SERVICES, and THE delivery of THESE services ~~for all projects approved and Certificates of Need issued~~ under Part 222 of the Code ~~which involve air ambulance services~~.

~~(2)~~ PURSUANT TO PART 222 OF THE CODE, Air ambulance is a covered clinical ~~service for purposes of Part 222 of the Code.~~

~~(3) The~~service. The Department shall use ~~sections 3, 4, 5, 6, and 9, as applicable,~~THESE STANDARDS in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled ~~Laws.~~

~~(4) The Department shall use Section 8, as applicable, in applying~~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) "Acquisition of an existing air ambulance service" means obtaining possession and control of an existing air ambulance service by contract, ownership, lease or other comparable arrangement.~~

(b) "Advanced life support services" means patient care that may include any care a paramedic is qualified to provide by paramedic education that meets the educational requirements established by the Department under Section 20912 of the Code, being Section 333.20912 of the Michigan Compiled Laws, or is authorized to provide by the protocols established by the local medical control authority under Section 20919 of the Code, being Section 333.20919 of the Michigan Compiled Laws, for a paramedic.

(c) "Advanced life support intercept" means the use of an air ambulance to provide advanced life support services to a patient at the scene of an emergency that does not involve the transport of that patient by air.

(d) "Air ambulance" means a rotary wing aircraft that is capable of providing treatment or transportation of a patient at or from the scene of an emergency. An air ambulance may also be used for the inter-facility transport of a patient requiring at minimum advanced life support. The term does not include an air ambulance licensed in a state other than Michigan that does not transport patients from the scene of an emergency in Michigan, except pursuant to mutual aid agreements, and which is not required to be licensed as an air ambulance under Part 209 of the Code, being Section 20901 et seq. of the Michigan Compiled Laws.

(e) "Air ambulance service" means providing at least advanced life support services utilizing an air ambulance(s) that operates in conjunction with a base hospital(s). Other functions of the service may include searches, emergency transportation of drugs, organs, medical supplies, equipment or personnel. An air ambulance service may operate a back-up air ambulance when the primary air ambulance(s) is not available or for a designated event with prior notification and approval from the local medical control authority.

(f) "Back-up air ambulance" means an air ambulance that is used to provide air ambulance services when the primary air ambulance is not available to provide air ambulance services. A back-up air

ambulance shall not be operated at the same time as the primary aircraft for the provision of air ambulance services except for a designated event.

(g) "Base hospital(s)" means the hospital or hospitals designated by the applicant in the CON application as the location(s) to which the majority of patient transports will be completed.

(h) "Base of operations" means the site or sites at which the air ambulance(s) and crew are located for the air ambulance service.

(i) "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.

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

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

(l) "Designated event" means a temporary event, such as an air show, of no more than seven (7) days in duration that requires the full-time on-site availability of an air ambulance.

(m) "Emergency" means a condition or situation in which an individual declares a need for immediate medical attention for any individual, or where that need is declared by emergency medical services personnel or a public safety official, pursuant to MCL 333.20904.

(n) "Existing air ambulance" means an operational air ambulance on the date which an application is submitted to the Department.

(o) "Existing air ambulance service" means an operational air ambulance service or an air ambulance service approved, but not yet operational on the date which an application is submitted to the Department.

~~(p) "Expand an air ambulance service" means increasing the number of air ambulances operated by an existing air ambulance service.~~

(~~q~~p) "Health facility" means a health facility or agency as defined in Section 20106 of the Code, being Section 333.20106 of the Michigan Compiled Laws.

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

~~(s) "Initiate an air ambulance service" means begin operation of an air ambulance service from a base of operations that does not provide air ambulance services in compliance with Part 222 of the Code and is not listed on the Department inventory of air ambulances on the date on which an application is submitted to the Department. The term does not include the renewal of a lease.~~

(~~t~~r) "Inter-facility transport" means the transport of a patient between health facilities using an air ambulance.

~~(u) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 TO 1396G and1396r-8~~ to1396v~~to1396u~~.

(~~v~~s) "Medical control authority" means an organization designated by the Department under Section 20910(1)(g) to provide medical control, pursuant to MCL 333.20906.

(~~w~~t) "Monitored bed" means a licensed hospital bed that has, at a minimum, the capability of electronically monitoring in real time a patient's cardiac activity.

(~~x~~u) "Mutual aid" means a written agreement between 2 or more air ambulance services for the provision of emergency medical services when an air ambulance service is unable to respond to a request for a pre-hospital transport.

(~~y~~v) "Organ transport" means the use of an air ambulance to transport an organ(s) and surgical transplant team between hospitals for transplantation purposes occurring in Michigan.

(~~z~~w) "Patient transport" means the use of an air ambulance to provide an advanced life support intercept, a pre-hospital transport or an inter-facility transport occurring in Michigan.

(~~aa~~x) "Pre-hospital transport" means the use of an air ambulance to provide transportation and advanced life support services to a patient from the scene of an emergency to a hospital.

~~(bb) "Replace an air ambulance" means an equipment change which results in an air ambulance service operating an air ambulance, with a different aircraft manufacturer's serial number, other than a back-up air ambulance.~~

(~~cc~~y) "Rotary wing aircraft" means a helicopter.

(2) The definitions of Part 209 and 222 shall apply to these standards.

Section 3. Requirements for approval to initiate an air ambulance service

Sec. 3. "Initiate an air ambulance service" means begin operation of an air ambulance service from a base of operations that does not provide air ambulance services in compliance with Part 222 of the Code and is not listed on the Department inventory of air ambulances on the date on which an application is submitted to the Department. The term does not include the renewal of a lease. An applicant proposing to initiate an air ambulance service shall:

(1) Operate only one (1) air ambulance.

(2) Identify the base hospital(s) of the proposed air ambulance service.

(3) Identify the base of operations of the proposed air ambulance service.

(4) Provide a letter of support from the medical control authority for the base of operations indicating that the applicant's proposed protocols comply with the requirements of the medical control authority.

~~(5) Project, in accordance with the methodology in Section 9, that at least 275 patient transports will be made in the second 12 months after beginning operation.~~

(~~6~~5) Demonstrate that all existing air ambulance services with a base of operations within a 75-mile radius of the base of operations of the proposed air ambulance service have been notified of the applicant's intent to initiate an air ambulance service, by means of certified mail return receipt, dated before the deemed complete date of the application.

Section 4. Requirements for approval to ~~expand~~ REPLACE an air ambulance service

Sec. 4. "Replace an air ambulance" means an equipment change which results in an air ambulance service operating an air ambulance, with a different aircraft manufacturer's serial number, other than a back-up air ambulance. An applicant proposing to replace an existing air ambulance shall: An applicant proposing to ~~expand~~ REPLACE an air ambulance service shall:

(1) ~~Demonstrate that in the most recent 12-month period for which verifiable data are available to the Department, the air ambulance service met one (1) of the following:~~

~~(a) 600 patient transports and organ transports for an air ambulance service expanding to two (2) air ambulances, of which 275 must be patient transports.~~

~~(b) 1,200 patient transports and organ transports for an air ambulance service expanding to three (3) air ambulances, of which 550 must be patient transports.~~

~~(c) 1,800 patient transports and organ transports for an air ambulance service expanding to four (4) air ambulances, of which 825 must be patient transports.~~ Demonstrate that the existing air ambulance to be replaced is fully depreciated according to generally accepted accounting principles, or that the replacement air ambulance offers significant technological improvements which enhance safety or quality of care, increases efficiency, or reduces operating costs.

(2) Identify the existing base of operations of the air ambulance service.

(3) ~~Identify any proposed base of operations and demonstrate that the proposed base of operations is within the same medical control authority as the existing base of operations.~~

~~(4)~~ Identify the existing ~~and proposed~~ base hospital(s) of the air ambulance service.

(4) Assert that the air ambulance to be replaced shall be removed from operation at the applicant's air ambulance service or designated as a back-up air ambulance.

(5) PROVIDE A LETTER OF SUPPORT FROM THE MEDICAL CONTROL AUTHORITY FOR THE BASE OF OPERATIONS INDICATING THAT THE APPLICANT'S PROPOSED PROTOCOLS COMPLY WITH THE REQUIREMENTS OF THE MEDICAL CONTROL AUTHORITY.

Section 5. Requirements for approval to ~~replace~~ EXPAND an air ambulance

Sec. 5. "Expand an air ambulance service" means increasing the number of air ambulances operated by an existing air ambulance service. An applicant proposing to ~~replace~~ EXPAND an existing air ambulance shall:

(1) ~~Demonstrate that in the most recent 12-month period for which verifiable data are available to the Department, the air ambulance service met one (1) of the following:~~

~~(a) 275 patient transports for an air ambulance service with one (1) air ambulance.~~

~~(b) 600 patient transports and organ transports for an air ambulance service with two (2) air ambulances, of which 550 must be patient transports.~~

~~(c) 1,200 patient transports and organ transports for an air ambulance service with three (3) air ambulances, of which 825 must be patient transports.~~

~~(d) 1,800 patient transports and organ transports for an air ambulance service with four (4) air ambulances, of which 1,100 must be patient transports.~~

~~(2) Demonstrate that the existing air ambulance to be replaced is fully depreciated according to generally accepted accounting principles, or that the replacement AIR AMBULANCE offers significant technological improvements which enhance safety or quality of care, increases efficiency, or reduces operating costs.~~

~~(3)~~ Identify the existing base of operations of the air ambulance service.

(2) Identify any proposed base of operations and demonstrate that the proposed base of operations is within the same medical control authority as the existing base of operations.

(~~4~~3) Identify the existing and proposed base hospital(s) of the air ambulance service.

(~~5~~4) ~~Assert that the air ambulance to be replaced shall be removed from operation at the applicant's air ambulance service or designated as a back-up air ambulance.~~PROVIDE A LETTER OF SUPPORT FROM THE MEDICAL CONTROL AUTHORITY FOR THE BASE OF OPERATIONS INDICATING THAT THE APPLICANT'S PROPOSED PROTOCOLS COMPLY WITH THE REQUIREMENTS OF THE MEDICAL CONTROL AUTHORITY.

Section 6. Requirements for approval to acquire an existing air ambulance service

Sec. 6. "Acquisition of an existing air ambulance service" means obtaining possession and control of an existing air ambulance service by contract, ownership, lease or other comparable arrangement. An applicant proposing to acquire an existing air ambulance service shall:

(1) ~~Demonstrate that in the most recent 12-month period for which verifiable data are available to the department, the air ambulance service met one (1) of the following:~~

~~(a) 275 patient transports for an air ambulance service with one (1) air ambulance.~~

~~(b) 600 patient transports and organ transports for an air ambulance service with two (2) air ambulances, of which 550 must be patient transports.~~

~~(c) 1,200 patient transports and organ transports for an air ambulance service with three (3) air ambulances, of which 825 must be patient transports.~~

~~(d) 1,800 patient transports and organ transports for an air ambulance service with four (4) air ambulances, of which 1,100 must be patient transports.~~

~~(2)~~ Identify the existing base of operations of the air ambulance service.

(~~3~~2) Identify any proposed base of operations and demonstrate that the proposed base of operations is within the same medical control authority as the existing base of operations.

(~~4~~3) Identify the existing and proposed base hospital(s) of the air ambulance service.

(~~5~~4) Provide a letter of support from the medical control authority for the base of operations indicating that the applicant's proposed protocols comply with the requirements of the medical control authority.

Section 7. Requirements for ~~approval for all applicants~~MEDICAID PARTICIPATION

Sec. 7. 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 8. Project delivery requirements--terms of approval for all applicants

Sec. 8. ~~(1)~~ An applicant shall agree that, if approved, the AIR AMBULANCE services ~~provided by the air ambulance service~~ shall be delivered in compliance with the following terms of ~~CON~~ approval:

(~~a~~1) Compliance with these standards.

(2) COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE REQUIREMENTS:

(~~b~~a) Compliance with applicable state and federal safety, operating, and licensure standards.

(~~c~~b) Compliance with applicable local medical control authority protocols for scene responses by air ambulances.

~~(d) An average of 275 patient transports annually for each existing air ambulance.~~

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

(i) The applicant shall be accredited as an air ambulance service by the Commission on the Accreditation of Medical Transport Systems (CAMTS) within 2 years of beginning operation; or

(ii) the applicant shall maintain the following:

(A) written policies and procedures specifying the levels of patient care to be provided. The level of patient care provided shall be commensurate with the education and experience of the staff and the capabilities of the base hospitals.

(B) written patient care protocols including provisions for continuity of care;

(C) written policies and procedures that define the roles and responsibilities of all staff members;

(D) written policies and procedures addressing the appropriate use of air ambulance services;

(E) a written communicable disease and infection control program;

(F) a written plan for dealing with situations involving hazardous materials;

(G) a planned and structured program for initial and continuing education and training, including didactic, clinical and in-flight, for all scheduled staff members appropriate for the respective duties and responsibilities;

(H) written policies and procedures addressing the integration of the air ambulance service with public safety agencies governing the base hospitals including but not limited to the federal aviation administration, medical control authorities, ground emergency vehicles and disaster planning;

(I) a quality management program;

(J) a clinical data base for utilization review and quality assurance purposes; and

(K) procedures to screen patients to assure appropriate utilization of the air ambulance service.

(~~f~~d) Compliance with staffing and essential equipment as required by Part 209 of the Code, being Section 20901 et seq. of the Michigan Compiled Laws.

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

(~~g~~a) Compliance with all appropriate requests for services for pre-hospital transports.

(~~h~~b) Assurance that an air ambulance service will be utilized by all segments of the Michigan population, shall:

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

(ii) provide air ambulance services to any individual based on ~~the~~ clinical ~~indications~~ NECESSITY ~~of need for the service~~; and

(III) ~~Participation~~PARTICIPATE in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

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

(~~i~~a) Participation 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. 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.

(~~j~~b) ~~Provision of notice to~~THE APPLICANT SHALL PROVIDE the Department with ~~a~~ TIMELY notice ~~stating the date the new, additional, or replacement air ambulance, is placed in operation and such notice shall be submitted to the Department~~ OF THE PROPOSED PROJECT IMPLEMENTATION consistent with applicable statute and promulgated rules.

~~(k) Participation in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.~~

(~~2~~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 9. Methodology for projecting patient transports**~~

~~Sec. 9. An applicant required to project patient transports shall compute projected patient transports as follows:~~

~~(1) Identify the base hospital(s) to which patient transports will be completed by the proposed air ambulance service.~~

~~(2) In order to include data from any hospital, an applicant shall document in the application each hospital's intent to utilize the proposed air ambulance service. For each hospital from which patients will be transported to a base hospital(s), document each of the following:~~

~~(a) The number of patients that were transferred to each base hospital and either admitted to a monitored bed or expired prior to admission during the most recent 12-month period preceding the date on which an application is submitted to the Department.~~

~~(b) The number of patients identified in subdivision (a) that were transferred by ground transportation.~~

~~(c) The number of patients identified in subdivision (b) for which air transport would have been appropriate and for which an existing air ambulance service within a 75-mile radius was unavailable for reasons other than weather.~~

~~(3) An applicant shall document the number of patients transferred from the scene of an emergency by ground transport to the base hospital(s) for which air transport would have been appropriate and for which an existing air ambulance service within a 75-mile radius was unavailable for reasons other than weather and the patients were either admitted to a monitored bed or expired prior to admission during the most recent 12-month period preceding the date on which an application is submitted to the Department.~~

~~(4) The projected number of patient transports shall be the sum of the results of subsections (2)(c) and (3).~~

Section ~~10~~9. Effect on Prior CON Review Standards; Comparative reviews

Sec. ~~10~~9. (1) These CON review standards supersede and replace the CON Review Standards for Air Ambulance Services approved by the CON Commission on ~~March 9, 2004~~ JUNE 10, 2010 and effective on ~~June 4, 2004~~AUGUST 12, 2010.

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

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

Date: February 20, 2014

TO: Brenda Rogers

FROM: Natalie Kellogg

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

---

Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the CT Scanner Services Standards at its December 12, 2013 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed CT Scanner Services Standards on January 22, 2014. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was not received from any organizations.

Recommendations

The Department recommends that the Commission take final action to approve the language as presented at the December 12, 2013 meeting.

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, ~~relocation,~~ 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 ~~under procedure codes in effect on December 31, 2010,~~ 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.

(~~d~~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.

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

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

(~~g~~h) "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.

(~~h~~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 ~~21~~22.

(~~i~~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.

(~~j~~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.

(~~k~~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.

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

(~~m~~o) "Dental procedures" means dental implants, wisdom teeth surgical procedures, mandibular or maxillary surgical procedures, or temporal mandibular joint evaluations.

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

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

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

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

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

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

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

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

(~~v~~x) "Health Service Area" or "HSA" means the groups of counties listed in ~~Section 24~~APPENDIX A.

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

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

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

(~~z~~bb) "Initiate a CT scanner service" means to begin operation of a CT scanner, whether fixed or mobile, at a site that does not perform CT scans as of the date an application is submitted to the Department. The term does not include the acquisition or ~~relocation~~ REPLACEMENT of an existing CT scanner service AT THE EXISTING SITE OR TO A DIFFERENT SITE or the renewal of a lease.

(~~aa~~cc) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396~~r-6 and1396r-8~~ to ~~1396v~~1396w-5.

~~(bb) "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.~~

~~(cc) "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.~~

(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) "Relocate a fixed CT scanner" means a change in the location of a fixed CT scanner from the existing site to a different site within the relocation zone.~~

~~(hh) "Relocate an existing CT scanner service" means a change in the geographic location of an existing fixed CT scanner service from an existing site to a different site.~~

~~(ii) "Relocation zone," means a site that 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.~~

(~~jj~~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.

~~(kk) "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.~~

(~~ll~~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).

(~~mm~~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 ~~other than a dental CT scanner service or hospital-based portable 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 ~~each of~~ 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 APPICANT 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~~fixed~~ 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 APPICANT 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 ~~other than a dental CT scanner service or hospital-based portable 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 ~~17~~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 ~~17~~ 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 ~~other than a dental CT scanner or hospital-based portable CT scanner~~

Sec. 7. An applicant proposing to replace an existing CT scanner OR SERVICE~~, EXCEPT FOR AN APPLICANT APPROVED UNDER SECTION 3(1),~~ OTHER THAN A DENTAL CT SCANNER SERVICE OR A HOSPITAL-BASED PORTABLE CT SCANNER SERVICE, shall demonstrate ~~each of~~ the following, as applicable:

(1) An applicant~~, other than an applicant meeting all of the applicable requirements of subsection (a), (b) or (c) below,~~ proposing to replace an existing fixed, MOBILE, OR DEDICATED PEDIATRIC CT scanner shall demonstrate ~~that the fixed CT scanner(s) performed at least an average of 7,500 CT equivalents per fixed CT scanner in the most recent 12-month period for which the Department has verifiable data.~~

~~(a) A hospital proposing to replace an existing CT scanner which is the only fixed CT scanner operated at that site by the hospital shall demonstrate each~~ALL of the following:

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

~~(ii) 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.~~

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

~~(b) An applicant proposing to replace an existing fixed CT scanner shall be exempt once from the volume requirements if the existing CT scanner demonstrates that it meets all of the following:~~

~~(i) The existing CT scanner has performed at least 5,000 CT equivalents in the most recent 12-month period for which the Department has verifiable data.~~

~~(ii) The existing CT scanner is fully depreciated according to generally accepted accounting principles.~~

~~(iii) The existing CT scanner has at one time met its minimum volume requirements.~~

~~(c) An applicant proposing to replace an existing fixed CT scanner on an academic medical center campus, at the same site, shall be exempt once, as of May 5, 2008, from the minimum volume requirements for replacement if the existing CT scanner is fully depreciated according to generally accepted accounting principles.~~

~~(d) An applicant proposing to replace an existing fixed CT scanner having a configuration of less than 16 multi-detector rows shall be exempt once, as of the effective date of the standards, from the minimum volume requirements for replacement if it meets both of the following:~~

~~(i) The proposed CT scanner to be obtained will have a configuration of sixteen (16) or more multi-detector rows, and~~

~~(ii) The existing CT scanner is fully depreciated according to generally accepted accounting principles.~~

~~(2) An applicant proposing to replace an existing mobile CT scanner(s) shall demonstrate that the mobile CT scanner(s) performed at least 3,500 CT equivalents if the applicant operates only one mobile CT scanner or an average of 5,500 CT equivalents for each CT scanner if the applicant operates more than one mobile CT scanner for the same mobile CT scanner network, in the most recent 12-month period for which the department has verifiable data.~~

~~(3) An applicant proposing to replace an existing dedicated pediatric CT scanner(s) shall demonstrate that the dedicated pediatric CT scanner(s) performed at least an average of 2,500 CT equivalents per dedicated pediatric CT scanner in the most recent 12-month period for which the Department has verifiable data.~~

(4b) ~~An applicant under this section shall demonstrate that t~~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 ~~relocate~~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 ~~relocated~~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 in the relocation zone~~ 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 requirements of sections 5 or 7, as applicable, have been met.~~

(~~d~~c) The CT scanner service to be ~~relocate~~REPLACED~~d~~ 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).

(~~e~~d) The applicant agrees to operate the CT scanner service in accordance with all applicable project delivery requirements set forth in Section ~~19~~20 of these standards.

(3) An applicant proposing to ~~relocate~~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 ~~relocated~~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 in the relocation zone~~ 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 requirements of sections 5 or 7, as applicable, have been met.~~
(~~d~~c) Each existing CT scanner at the service from which a scanner is to be ~~relocated~~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.
(~~e~~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 ~~19~~20 of these standards.
(~~f~~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 ~~each of~~ the following, AS APPLICABLE:

(1) An applicant proposing to replace an existing fixed OR MOBILE dental CT scanner shall demonstrate ~~that the fixed OR MOBILE dental CT scanner(s) performed at least an average of 200 dental CT examinations per fixed OR MOBILE dental CT scanner in the most recent 12-month period for which the Department has verifiable data.~~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.

(~~2~~b) ~~An applicant under this section shall demonstrate that t~~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 ~~relocate~~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 ~~relocated~~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 ~~in the relocation ZONE~~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 requirements of sections 6 or 8, as applicable, have been met.~~
(~~d~~c) The dental CT scanner service to be REPLACED ~~relocated~~ 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~~d) The applicant agrees to operate the dental CT scanner service in accordance with all applicable project delivery requirements set forth in Section ~~19~~20 of these standards.

(3) An applicant proposing to ~~relocate~~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 ~~relocated~~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 ~~in the relocation zone~~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) The requirements of sections 6 or 8, as applicable have been met.~~

(~~e~~d) Each existing dental CT scanner at the service from which a scanner is to be ~~relocated~~ 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.

(~~f~~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 ~~19~~20 of these standards.

~~**Section 9. Requirements for approval for applicants proposing to relocate an existing CT scanner service and/or CT scanner(s) other than an existing dental CT scanner service and/or dental CT scanner(s) or hospital-based portable CT scanner(s)**~~

~~Sec. 9. (1) An applicant proposing to relocate an existing fixed CT scanner service shall demonstrate that the proposed project meets all of the following:~~

~~(a) The existing fixed CT scanner service 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 proposed new site is in the relocation zone.~~

~~(c) The requirements of sections 5 or 7, as applicable, have been met.~~

~~(d) The CT scanner service to be relocated 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.~~

~~(e) The applicant agrees to operate the CT scanner service in accordance with all applicable project delivery requirements set forth in Section 19 of these standards.~~

~~(2) An applicant proposing to relocate a fixed CT scanner(s) of an existing CT scanner service 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 relocated 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 in the relocation zone.~~

~~(c) The requirements of sections 5 or 7, as applicable, have been met.~~

~~(d) Each existing CT scanner at the service from which a scanner is to be relocated 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.~~

~~(e) 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 19 of these standards.~~

~~**Section 10. Requirements for approval for applicants proposing to relocate an existing dental CT scanner service and/or dental CT scanner(s)**~~

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

~~(a) The existing fixed dental CT scanner service to be relocated 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 in the relocation zone.~~
~~(c) The requirements of sections 6 or 8, as applicable, have been met.~~
~~(d) The dental CT scanner service to be relocated 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 service in accordance with all applicable project delivery requirements set forth in Section 19 of these standards.~~

~~(2) An applicant proposing to relocate a fixed dental CT scanner(s) of an existing dental CT scanner service 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 relocated 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 in the relocation zone.~~
~~(c) The requirements of sections 6 or 8, as applicable have been met.~~
~~(d) Each existing dental CT scanner at the service from which a scanner is to be relocated 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 19 of these standards.~~

Section ~~11~~9. Requirements for approval for applicants proposing to acquire an existing CT scanner service or an existing CT scanner(s) ~~other than an existing dental CT scanner service and/or an existing dental CT scanner(s) or hospital-based portable CT scanner(s)~~

Sec. ~~11~~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~~, EXCEPT FOR AN APPLICANT APPROVED UNDER SECTION 3(1),~~ shall demonstrate that a proposed project meets all of the following:
~~(a) The requirements of sections 5, 7, or 9, as applicable, have been met.~~
(~~b~~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 ~~19~~ 20 of these standards in the second 12 months after the date the service is acquired, and annually thereafter.
(~~c~~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) ~~that the~~ The MOBILE CT scanner service to be acquired performed at least ~~7~~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 ~~all of~~ the following:
~~(a) The requirements of sections 5, 7 or 9, as applicable, have been met.~~

(~~b~~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) ~~that t~~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 ~~or~~.

(ii) THE mobile CT scanner(s) to be acquired performed at least ~~7~~3,500 CT equivalents PER MOBILE CT SCANNER in the most recent 12-month period for which the Department has verifiable data.

Section ~~12~~10. Requirements for approval for applicants proposing to acquire an existing dental CT scanner service or an existing dental CT scanner(s)

Sec. ~~12~~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) ~~The requirements of sections 6 OR, 8, or 10, as applicable, have been met.~~

~~(b)~~ 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 ~~19~~ 20 of these standards in the second 12 months after the date the service is acquired, and annually thereafter.

(~~c~~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 ~~all of~~ the following:

(a) ~~The requirements of sections 6 OR, 8, or 10, as applicable, have been met.~~

~~(b)~~ 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 ~~19~~20(~~46~~).

(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. ~~Pilot program requirements~~ Requirements for approval of a hospital-based portable CT scanner for initiation, expansion, replacement, and acquisition

Sec. 13. ~~As a pilot program, a~~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 ~~19~~ 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.

~~(7) The Commission may decide to have the requirements of the pilot program described in this section become a permanent part of the CT scanner services standards. If the Commission does not take action to make the pilot program a permanent part of the standards, the provisions of Section 13, as part of a pilot program, will expire on December 31, 2016 and be of no further force and effect after December 31, 2016. Any applicant seeking to be part of the pilot program described in this section must submit its application on or before December 1, 2013. These provisions shall not be applicable to any application which has not been submitted by December 1, 2013.~~

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 ~~19~~ 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 ~~15~~16. Additional requirements for approval of a mobile CT scanner service

Sec. ~~15~~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.

~~(c) The requirements of sections 3, 5, or 7, as applicable, have been met.~~

(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.

~~(3) An applicant proposing to replace a central service coordinator on an existing mobile CT scanner network shall demonstrate that approval of the application will not replace the CT scanner and transporting equipment unless the applicable requirements of Section 7 have been met.~~

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 1615~~. ~~Requirements for approval of an applicant proposing a CT scanner used for the sole purpose of performing dental CT examinations exclusively for research~~

~~Sec. 1615. (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 19(4).~~

~~(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 ~~17~~18. Requirements for approval of an applicant proposing to establish dedicated pediatric CT Scanner

Sec. ~~17~~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 ~~18~~19. Requirements ~~-~~ for MEDICAID ~~approval -- all applicants~~PARTICIPATION

Sec. ~~18~~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 ~~19~~20. Project delivery requirements ~~--~~ AND terms of approval for all applicants

Sec. ~~19~~20. ~~(1)~~ An applicant shall agree that, if approved, the ~~services provided by the~~ CT scanner(s) SERVICES shall be delivered in compliance with the following terms of ~~CON~~ approval~~:~~.

(~~a~~1) Compliance with these standards.

~~(b) Compliance with applicable safety and operating standards~~

(~~c~~2) Compliance with the following quality assurance standards:

~~(i) The approved CT scanners shall be operating at the applicable required volumes within the time periods specified in these standards, and annually thereafter.~~

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

(~~A~~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

(~~B~~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 (~~ii~~a)(~~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 (~~ii~~a)(~~B~~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.

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

(~~iv~~c) The applicant shall assure that at least one of the physicians responsible for the screening and interpretation as defined in subsection (~~ii~~a)(~~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.

(~~v~~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 (~~ii~~a)(~~A~~i) within 24 hours.

(~~vi~~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.

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

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

(~~ix~~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.

(~~x~~i) An applicant approved under Section ~~17~~ 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:

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

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

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

(~~C~~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:

(~~i~~a) The approved CT scanners shall be operating at ~~the applicable required volumes~~AN AVERAGE ~~within the time periods specified in these standards,~~ 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.

(~~xiib~~) 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.

(~~xiic~~) Equipment to be replaced shall be removed from service.

(~~xivd~~) The applicant shall provide the Department with ~~a~~ TIMELY notice ~~stating the date the approved CT scanner service is placed in operation and such notice shall be submitted to the Department~~ OF THE PROPOSED PROJECT IMPLEMENTATION consistent with applicable statute and promulgated rules.

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

(~~de~~) An applicant approved under Section 4 shall not be required to be in compliance with subsection (~~c~~2). ~~but shall be in compliance with the following quality assurance standards:~~

~~(i) 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.~~

(5) COMPLIANCE WITH THE FOLLOWING DENTAL CT SCANNER (FIXED OR MOBILE) REQUIREMENTS, IF APPLICABLE:

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

(~~iii~~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.

(~~iv~~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.

(~~v~~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.

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

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

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

(~~C~~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.

(~~vii~~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.

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

((~~ix~~i) The applicant shall provide the Department with ~~a~~ TIMELY notice ~~stating the date the approved dental CT scanner service is placed in operation and such notice shall be submitted to the Department~~ OF THE PROPOSED PROJECT IMPLEMENTATION consistent with applicable statute and promulgated rules.

(~~x~~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.

~~(2ei) 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.~~

~~(3) 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).~~

(~~4~~6) An applicant for a CT scanner used for dental research under Section ~~16~~12(1) shall agree that the services provided by the CT scanner approved pursuant to Section ~~16~~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 ~~16~~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 ~~16~~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 ~~16~~12.

(~~5~~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 ~~pilot~~ 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 ~~and begins with 2010 data which is to be reported in 2011~~.

(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

~~(iv) Number of patients scanned on a portable CT that underwent subsequent scanning on a fixed CT within 12 hours of the portable CT scan~~

(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

(~~2~~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 ~~20~~21. Project delivery requirements AND additional terms of approval for applicants involving mobile CT scanners

Sec. ~~20~~21. (1) In addition to the provisions of Section ~~19~~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 ~~19~~20(~~1~~2)(~~e~~i)~~(xi)~~.

(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 ~~21~~22. Determination of CT Equivalents

Sec. ~~21~~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
ADULT PATIENT					
Head Scans w/o Contrast (includes dental CT examinations)	_____	X	1.00	=	_____
Head Scans with Contrast	_____	X	1.25	=	_____
Head Scans w/o & w Contrast	_____	X	1.75	=	_____
Body Scans w/o Contrast	_____	X	1.50	=	_____
Body Scans with Contrast	_____	X	1.75	=	_____
Body Scans w/o & w Contrast	_____	X	2.75	=	_____
BUNDLED BODY SCAN	_____	X	3.50	=	_____
PEDIATRIC/SPECIAL NEEDS PATIENT					
Head scans w/o Contrast (includes dental CT examinations)	_____	x	1.25	=	_____
~~Pediatric/Special Needs Patient~~ Head Scans with Contrast	_____	x	1.50	=	_____
~~Pediatric/Special Needs Patient~~ Head Scans w/o & with Contrast	_____	x	2.00	=	_____
~~Pediatric/Special Needs Patient~~ Body Scans w/o Contrast	_____	x	1.75	=	_____
~~Pediatric/Special Needs Patient~~ Body Scans with Contrast	_____	x	2.00	=	_____
~~Pediatric/Special Needs Patient~~ Body Scans w/o & with Contrast	_____	x	3.00	=	_____
BUNDLED BODY SCAN	_____	X	4.00	=	_____
Total CT Equivalents					_____

Section ~~22~~23. Documentation of projections

Sec. ~~22~~23. An applicant required to project volumes under sections 3~~,~~ AND 4 ~~and 5~~ 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 required to project under Section 5 shall demonstrate that the projection is based on historical utilization at the applicant's site for the most recent 12-month period immediately preceding the date of the application.~~

(~~4~~3) An applicant shall demonstrate that the projected number of referrals to be performed at the proposed site under subsection~~s~~ (1) ~~and (2)~~ 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 ~~23~~24. Effect on prior CON review standards; comparative reviews

Sec. ~~23~~24. (1) These CON review standards supersede and replace the CON Review Standards for Computed Tomography Scanner Services approved by the CON Commission on ~~April 30, 2008~~DECEMBER 15, 2011 and effective on ~~June 20, 2008~~FEBRUARY 27, 2012.

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

APPENDIX A

~~**Section 24. Health Service Areas**~~

~~Sec. 24.~~ Counties assigned to each of the health service areas are as follows:

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

APPENDIX ~~A~~ B

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:
65 F.R., p. 82238 (December 27, 2000)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

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

Date: February 20, 2014

TO: Brenda Rogers

FROM: Natalie Kellogg

RE: Summary of Public Hearing Comments on Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services Standards

---

Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the UESWL Services Standards at its December 12, 2013 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed UESWL Services Standards on January 22, 2014. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was not received from any organizations.

Recommendations

The Department recommends that the Commission take final action to approve the language as presented at the December 12, 2013 meeting.

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. ~~(1)~~ These standards are requirements for approval TO INITIATE, REPLACE, EXPAND, OR ACQUIRE AN UESWL SERVICE/UNIT ~~and delivery of services for all projects approved and Certificates of Need issued~~ under Part 222 of the Code. ~~that involve a urinary extracorporeal shock wave lithotripsy service/unit.~~

~~(2)~~ Urinary extracorporeal shock wave lithotripsy is a covered clinical service for purposes of Part 222 of the Code.

~~(3)~~ The Department shall use ~~sections 3, 4, 5, 6, 7, 8, 12, 13, 14, and 15, as applicable,~~THESE STANDARDS in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws~~.~~

~~(4) The Department shall use sections 10~~ and ~~11, as applicable, in applying~~ Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

~~(5) The Department shall use Section 9, as applicable, in applying Section 22215(1)(b) of the Code, being Section 333.22215(1)(b) of the Michigan Compiled Laws.~~

Section 2. Definitions

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

~~(a) "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.~~

(~~b~~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.

(~~c~~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.

(~~d~~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.

(~~e~~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.

(~~f~~e) "Department" means the Michigan Department of Community Health (MDCH).

(~~g~~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.

(~~h~~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.

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

~~(j) "Expand an existing UESWL service" means the addition of one UESWL unit at an existing UESWL service.~~

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

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

~~(m) "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 relocation of an existing UESWL service or the renewal of a lease.~~

(~~n~~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.

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

~~(p) "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 B.~~

(~~o~~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.

~~(r) "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 B.~~

(~~s~~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.

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

(~~u~~o) "Region" means the geographic areas set forth in ~~Section 12~~APPENDIX B.

~~(v) "Relocate a fixed UESWL unit" means a change in the location of a fixed UESWL unit(s) from the existing site to a different site within the relocation zone.~~

~~(w) "Relocate an existing UESWL service" means a change in the geographic location of an existing fixed UESWL service and its unit(s) from an existing site to a different site.~~

~~(x) "Relocation zone" means the geographic area that is within a 25-mile radius, within the state of Michigan, of the existing site of the UESWL service to be relocated.~~

(~~y~~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 ~~2(1)(z)~~4, or a change in the parties to the lease.

~~(z) "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.~~

(~~aa~~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.

~~(bb) "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.~~

~~(cc) "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.~~

(~~dd~~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.

(~~ee~~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.

(~~ff~~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.

(~~gg~~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 ~~for approval for all applicants proposing~~ to initiate a urinary extracorporeal shock wave lithotripsy service

Sec. 3. ~~(1)~~ 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 ~~relocation~~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 ~~13~~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 ~~for approval for applicants proposing~~ 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~~within the relocation zone.~~, 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 ~~13~~10.

(~~2~~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.

(~~3~~4) An applicant that demonstrates that it meets the requirements in this subsection shall not be required to demonstrate compliance with Section 4(~~1~~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 ~~13~~ 10 are combined for the following, as applicable:
(i) All licensed hospital sites committing MIDB data pursuant to Section ~~14~~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 ~~13~~10.

(~~4~~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 requirements of Sections 4 and 8, as applicable, have been met.~~
(~~d~~c) The site to which the UESWL service will be relocated meets the requirements of Section 3(1)(c).
(e) The proposed new site is in ~~the relocation zone within a 25-mile radius, within~~ the state of Michigan~~,~~ AND WITHIN A 25-MILE RADIUS of the existing site of the UESWL service to be relocated.
(~~e~~f) 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~~g) The applicant agrees to operate the UESWL service and its unit(s) in accordance with all applicable project delivery requirements set forth in Section ~~10~~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 requirements of Sections 4 and 8, as applicable, have been met.~~
(~~c~~b) The site to which the UESWL unit(s) will be relocated meets the requirements of Section 3(1)(c).

(~~d~~c) The proposed new site is in ~~the relocation zone within a 25-mile radius, within~~ the state of Michigan~~,~~ AND WITHIN A 25-MILE RADIUS of the existing site of the FIXED UESWL ~~service~~UNIT to be relocated.

(~~e~~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.

(~~f~~e) The applicant agrees to operate the UESWL unit(s) in accordance with all applicable project delivery requirements set forth in Section ~~10~~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. ~~8~~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 ~~13~~ 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 ~~5~~7(1)(c).

~~**Additional requirements for approval for mobile UESWL services**~~

~~Sec. 5. (1) An applicant proposing to begin operation of a mobile UESWL service in Michigan shall demonstrate that it meets all of the following:~~

~~(a) The proposed mobile UESWL service meets the requirements of Section 3 or 4, as applicable.~~

~~(b) 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 13 are combined for the following, as applicable:~~

~~(i) All licensed hospital sites committing MIDB data pursuant to Section 14, 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).~~

~~(c) 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 subsection (1)(a) and (1)(b) 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 13 are combined for the following, as applicable:~~
~~(a) All licensed hospital sites committing MIDB data pursuant to Section 14, 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 6. Requirements ~~for approval for applicants proposing~~ to acquire an existing UESWL service and ~~its unit(s)~~ 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) ~~The requirements of Sections 4 and 7, as applicable, have been met.~~
~~(b)~~ 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 ~~10~~ 9 of these standards in the second 12 months after the date the service and its unit(s) is acquired, and annually thereafter.
(~~c~~b) For any application for proposed acquisition of an existing fixed or mobile UESWL service, except the first application approved pursuant to subsection (~~3~~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) ~~The requirements of Section 4 and 7, as applicable, have been met.~~
~~(b)~~ 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.
(~~c~~b) The requirements of Section 3(1)(c) have been met.

Section 7. ~~Requirements for approval for applicants proposing to relocate an existing UESWL service and/or UESWL unit(s)~~

~~Sec. 7. (1) 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 requirements of Sections 4 and 8, as applicable, have been met.~~
~~(d) The site to which the UESWL service will be relocated meets the requirements of Section 3(1)(c).~~
~~(e) The proposed new site is in the relocation zone.~~
~~(f) 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.~~
~~(g) The applicant agrees to operate the UESWL service and its unit(s) in accordance with all applicable project delivery requirements set forth in Section 10 of these standards.~~

~~(2) 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 requirements of Sections 4 and 8, as applicable, have been met.~~
~~(c) The site to which the UESWL unit(s) will be relocated meets the requirements of Section 3(1)(c).~~
~~(d) The proposed new site is in the relocation zone.~~
~~(e) 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.~~
~~(f) The applicant agrees to operate the UESWL unit(s) in accordance with all applicable project delivery requirements set forth in Section 10 of these Standards.~~ **Additional requirements for approval for mobile UESWL services**

Sec. ~~5~~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) The proposed mobile UESWL service meets the requirements of Section 3 or 4, as applicable.~~
(~~b~~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 ~~13~~10 are combined for the following, as applicable:
(i) All licensed hospital sites committing MIDB data pursuant to Section ~~14~~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).
(~~c~~b) The normal route schedule, the procedures for handling emergency situations, and copies of all potential contracts related to the mobile UESWL service and its unit(s) shall be included in the CON application submitted by the central service coordinator.

(2) The requirements of SECTIONS 3, 4, AND subsection (1)(a) ~~and (1)(b)~~ 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 ~~13~~ 10 are combined for the following, as applicable:

(a) All licensed hospital sites committing MIDB data pursuant to Section ~~14~~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 approval to expand an existing UESWL service~~

~~Sec. 8. 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 13 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 5(1)(c).~~

~~Section 9.~~ Requirements for ~~approval – all applicants~~MEDICAID PARTICIPATION

Sec. ~~9~~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 ~~10~~9. Project delivery requirements ~~--~~ terms of approval for all applicants

Sec ~~10~~9. ~~(1)~~ An applicant shall agree that, if approved, UESWL SERVICES, INCLUDING ALL EXISTING AND APPROVED UESWL UNITS, ~~the project~~ shall be delivered in compliance with the following ~~terms of CON approval~~:

(~~a~~1) Compliance with these standards.

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

(~~c~~2) Compliance with the following quality assurance standards:

(~~i~~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.~~

(~~ii~~b) 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.

(~~iii~~c) An applicant shall accept referrals for UESWL services from all appropriately licensed health care practitioners.

(~~iv~~d) 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.

(~~v~~e) 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.

(~~vi~~f) 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.

(~~vii~~g) 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 (~~vi~~f), that a urologist on an applicant facility's active medical staff must meet in order to perform UESWL procedures.

(~~viii~~h) An applicant shall provide UESWL program access to approved physician residency programs for teaching purposes.

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

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

(~~A~~i) Not deny ANY UESWL services to any individual based on inability to pay or source of payment,

(~~B~~ii) Provide ALL UESWL services to any individual based on clinical indications of need for the services, and

(~~C~~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.

(~~x~~b) ~~An~~ 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.

(~~xi~~c) The applicant shall provide the Department with ~~a~~ TIMELY notice ~~stating the date the approved UESWL service and its unit(s) is placed in operation and such notice shall be submitted to the Department~~OF THE PROPOSED PROJECT IMPLEMENTATION consistent with applicable statute and promulgated rules.

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

~~(2) 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).~~

(~~3~~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. Project delivery requirements - additional terms of approval for applicants involving mobile UESWL services~~

~~Sec. 11. (1) In addition to the provisions of Section 10, an applicant for a mobile UESWL service shall agree that the services provided by the mobile UESWL unit(s) shall be delivered in c~~Compliance with the following MOBILE UESWL ~~terms of CON approval~~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.

(~~2~~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. Regions~~

~~Sec. 12. The counties assigned to each region are as follows:~~

~~Region~~	~~Counties~~
~~1~~	~~Livingston Monroe Macomb Oakland St. Clair Washtenaw Wayne~~
~~2~~	~~Clinton Eaton Hillsdale Ingham Jackson Lenawee~~
~~3~~	~~Barry Berrien Branch Calhoun Cass Kalamazoo St. Joseph Van Buren~~
~~4~~	~~Allegan Ionia Kent Lake Mason Mecosta Montcalm Muskegon Newaygo Oceana Osceola Ottawa~~

5	Genesee	Lapeer	Shiawassee		
6	Arenac	Bay	Clare	Gladwin	
	Gratiot	Huron	Iosco	Isabella	
	Midland	Ogemaw	Roscommon	Saginaw	
	Sanilac	Tuscola			
7	Alcona	Alpena	Antrim	Benzie	
	Crawford	Charlevoix	Cheboygan	Emmet	
	Gd. Traverse	Kalkaska	Leelanau	Manistee	
	Missaukee	Montmorency	Oscoda	Otsego	
	Presque Isle	Wexford			
8	Alger	Baraga	Chippewa	Delta	
	Dickinson	Gogebic	Houghton	Iron	
	Keweenaw	Luce	Mackinac	Marquette	
	Menominee	Ontonagon	Schoolcraft		

Section 1310. Methodology for projecting UESWL procedures

Sec. 1310. (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 1411. 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 1411. Requirements for MIDB data commitments

Sec. ~~14~~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 ~~15~~12. Effect on prior planning policies; comparative reviews

Sec. ~~15~~12. (1) These CON review standards supersede and replace the CON review standards for urinary extracorporeal shock wave lithotripsy (UESWL) services approved by the CON Commission on ~~March 9, 2004~~ DECEMBER 11, 2007 and effective on ~~June 4, 2004~~ FEBRUARY 25, 2008.

(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 ~~13~~10(1)(b) used for calculating the projected number of UESWL procedures shall be ~~.94~~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 ~~preliminary~~ 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~~ the records from step (a)(i) ~~above will then be aggregated~~ by ZIP CODE "urban/rural" STATUS~~and zip code~~.

(iii) IDENTIFY THE ~~Zip~~ zip codes ~~that are totally~~IN WHICH ALL RECORDS ARE EITHER "urban" STATUS or "rural" STATUS. ~~will have the discharges~~AGGREGATE THE NUMBER OF RECORDS and ZIP CODE populations ~~aggregated for those respective groups~~SEPARATELY BY "URBAN/RURAL" STATUS.

(iv) For ~~the remaining~~ zip codes ~~with~~ HAVING RECORDS IN both "urban" and "rural" ~~components~~STATUS, CALCULATE the proportion of ~~the zip code in each part (urban or rural) will be calculated and applied to~~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 ~~for that~~OF EACH zip code BY ITS RESPECTIVE "URBAN" AND "RURAL" PROPORTIONS.

(v) ~~These will then be a~~Aggregate~~d by discharge~~THE RECORDS AND 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 ~~per 10,000 population~~. 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) ~~The percentage difference between "urban" and "rural" discharge rates will be applied to the rate~~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) ~~above~~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	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Mason	Schoolcraft
Emmet	Montcalm	Tuscola
Gladwin	Montmorency	
Gogebic	Oceana	

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

65 F.R., p. 82238 (December 27, 2000)
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.

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

Date: February 20, 2014

TO: Brenda Rogers

FROM: Natalie Kellogg

RE: Summary of Public Hearing Comments on Cardiac Catheterization (CC) Services, Hospital Beds, Open Heart Surgery (OHS) Services and Positron Emission Tomography (PET) Scanner Services Standards

---

Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the CC Services, Hospital Beds, OHS Services, and PET Scanner Services Standards at its December 12, 2013 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed CC Services, Hospital Beds, OHS Services, and PET Scanner Services Standards on January 22, 2014. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was not received from any organizations.

Recommendations

The Department recommends that the Commission take final action to approve the language as presented at the December 12, 2013 meeting.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR CARDIAC CATHETERIZATION 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 approval of the initiation, replacement, expansion, or acquisition of cardiac catheterization services, and the delivery of these services under Part 222 of the Code. Pursuant to Part 222 of the Code, cardiac catheterization services are 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) "Cardiac catheterization laboratory" or "laboratory" means an individual radiological room equipped with a variety of x-ray machines and devices such as electronic image intensifiers, high speed film changers and digital subtraction units to assist in performing diagnostic or therapeutic cardiac catheterizations or electrophysiology studies.

(b) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, performed on a patient during a single session in a laboratory. Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aides in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart. This term does not include "float catheters" that are performed at the bedside or in settings outside the laboratory or the implantation of cardiac permanent pacemakers and implantable cardioverter defibrillators (ICD) devices that are performed in an interventional radiology laboratory or operating room.

(c) "Cardiac catheterization service" means the provision of one or more of the following types of procedures: adult diagnostic cardiac catheterizations; pediatric diagnostic cardiac catheterizations; adult therapeutic cardiac catheterizations; and pediatric therapeutic cardiac catheterizations.

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

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

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

(g) "Diagnostic cardiac catheterization service" means providing diagnostic cardiac catheterization procedures on an organized, regular basis in a laboratory to diagnose anatomical and/or physiological problems in the heart. Procedures include the intra coronary administration of drugs; left heart catheterization; right heart catheterization; coronary angiography; diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic). A hospital that provides diagnostic cardiac catheterization services may also perform implantations of cardiac permanent pacemakers and ICD devices.

(h) "Electrophysiology study" means a study of the electrical conduction activity of the heart and characterization of atrial and ventricular arrhythmias obtained by means of a cardiac catheterization procedure. The term also includes the implantation of permanent pacemakers and ICD devices.

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

~~(j) "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.~~

(~~k~~j) " Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to 1396g and1396i to 1396u.

(~~l~~k) "Pediatric cardiac catheterization service" means providing cardiac catheterization services on an organized, regular basis to infants and children ages 18 and below, except for electrophysiology studies that are offered and provided to infants and children ages 14 and below, and others with congenital heart disease as defined by the ICD-9-CM codes (SEE APPENDIX B FOR ICD-10-CM CODES) of 426.7 (anomalous atrioventricular excitation), 427.0 (cardiac dysrythmias), and 745.0 through 747.99 (bulbus cordis anomalies and anomalies of cardiac septal closure, other congenital anomalies of heart, and other congenital anomalies of circulatory system).

(~~m~~l) “Primary percutaneous coronary intervention (PCI)” means a PCI performed on an acute myocardial infarction (AMI) patient with confirmed ST elevation or new left bundle branch block.

(~~n~~m) "Procedure equivalent" means a unit of measure that reflects the relative average length of time one patient spends in one session in a laboratory based on the type of procedures being performed.

(~~o~~n) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or physiological problems in the heart. Procedures include PCI, PTCA, atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD device implantations, transcatheter valve, other structural heart disease procedures, percutaneous transluminal coronary angioplasty (PTCA) and coronary stent implantation and left sided arrhythmia therapeutic procedures. The term does not include the intra coronary administration of drugs where that is the only therapeutic intervention.

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

Section 3. Requirements to initiate cardiac catheterization services

Sec. 3. An applicant proposing to initiate cardiac catheterization services shall demonstrate the following, as applicable to the proposed project.

(1) An applicant proposing to initiate an adult diagnostic cardiac catheterization service shall demonstrate the following as applicable to the proposed project:

(a) An applicant proposing to initiate a diagnostic cardiac catheterization service with a single laboratory in a rural or micropolitan statistical area county shall project a minimum of 500 procedure equivalents including 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(b) An applicant proposing to initiate a diagnostic cardiac catheterization service with a single laboratory in a metropolitan statistical area county shall project a minimum of 750 procedure equivalents that includes 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(c) An applicant proposing to initiate a diagnostic cardiac catheterization service with two or more laboratories shall project a minimum of 1,000 procedure equivalents per laboratory that includes 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(2) An applicant proposing to initiate an adult therapeutic cardiac catheterization service shall demonstrate the following:

(a) The applicant provides, is approved to provide, or has applied to provide adult diagnostic cardiac catheterization services at the hospital. The applicant must be approved for adult diagnostic cardiac catheterization services in order to be approved for adult therapeutic cardiac catheterization services.

(b) An applicant operating an adult diagnostic cardiac catheterization service has performed a minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterizations during the most recent 12-month period preceding the date the application was submitted to the Department if the service has been in operation more than 24 months.

(c) The applicant has applied to provide adult open heart surgery services at the hospital. The applicant must be approved for an adult open heart surgery service in order to be approved for an adult therapeutic cardiac catheterization service.

(d) The applicant shall project a minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterizations based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(3) An applicant proposing to initiate a pediatric cardiac catheterization service shall demonstrate the following:

(a) The applicant has a board certified pediatric cardiologist with training in pediatric catheterization procedures to direct the pediatric catheterization laboratory.

(b) The applicant has standardized equipment as defined in the most current American Academy of Pediatrics (AAP) guidelines for pediatric cardiovascular centers.

(c) The applicant has on-site ICU as outlined in the most current AAP guidelines above.

(d) The applicant has applied to provide pediatric open heart surgery services at the hospital. The applicant must be approved for a pediatric open heart surgery service in order to be approved for pediatric cardiac catheterization services.

(e) The applicant shall project a minimum of 600 procedure equivalents in the category of pediatric cardiac catheterizations based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

(4) An applicant proposing to initiate primary PCI service without on-site open heart surgery services shall demonstrate the following:

(a) The applicant operates an adult diagnostic cardiac catheterization service that has performed a minimum of 500 procedure equivalents that includes 400 procedure equivalents in the category of cardiac catheterization procedures during the most recent 12 months preceding the date the application was submitted to the Department.

(b) The applicant has at least two interventional cardiologists to perform the primary PCI procedures and each cardiologist has performed at least 75 PCI sessions annually as the primary operator during the most recent 24-month period preceding the date the application was submitted to the Department.

(c) The nursing and technical catheterization laboratory staff: are experienced in handling acutely ill patients and comfortable with interventional equipment; have acquired experience in dedicated interventional laboratories at an open heart surgery hospital; and participate in an un-interrupted 24-hour, 365-day call schedule. Competency shall be documented annually.

(d) The laboratory or laboratories are equipped with optimal imaging systems, resuscitative equipment, and intra-aortic balloon pump (IABP) support, and stocked with a broad array of interventional equipment.

(e) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management. Competency shall be documented annually.

(f) A written agreement with an open heart surgery hospital that includes all of the following:

(i) Involvement in credentialing criteria and recommendations for physicians approved to perform primary PCI procedures.

(ii) Provision for ongoing cross-training for professional and technical staff involved in the provision of primary PCI to ensure familiarity with interventional equipment. Competency shall be documented annually.

(iii) Provision for ongoing cross training for emergency department, catheterization laboratory, and critical care unit staff to ensure experience in handling the high acuity status of primary PCI patient candidates. Competency shall be documented annually.

(iv) Regularly held joint cardiology/cardiac surgery conferences to include review of all primary PCI cases.

(v) Development and ongoing review of patient selection criteria for primary PCI patients and implementation of those criteria.

(vi) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for prompt care.

(vii) Written protocols, signed by the applicant and the open heart surgery hospital, for the immediate transfer, within 1 hour from the cardiac catheterization laboratory to evaluation on site in the open heart surgery hospital, of patients requiring surgical evaluation and/or intervention 365 days a year. The protocols shall be reviewed and tested on a quarterly basis.

(viii) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for the provision of interventional procedures.

(g) A written protocol must be established and maintained for case selection for the performance of primary PCI.

(h) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid transfer from the emergency department to the cardiac catheterization laboratory must be developed and maintained so that door-to-balloon targets are met.

(i) At least two physicians credentialed to perform primary PCI must commit to functioning as a coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate with administrative and clinical staff in establishing and implementing protocols, call schedules, and quality assurance procedures pertaining to primary PCI designed to meet the requirements for this certification and in keeping with the current guidelines for the provision of primary PCI promulgated by the American College of Cardiology and American Heart Association.

(j) The applicant shall project a minimum of 36 primary PCI cases based on data from the most recent 12-month period preceding the date the application was submitted to the Department.

Section 4. Requirements to replace an existing cardiac catheterization service or laboratory

Sec. 4. Replacing a cardiac catheterization laboratory means a change in the angiography x-ray equipment or a relocation of the service to a new site. The term does not include a change in any of the other equipment or software used in the laboratory. An applicant proposing to replace a cardiac catheterization laboratory or service shall demonstrate the following as applicable to the proposed project:

(1) An applicant proposing to replace cardiac catheterization laboratory equipment shall demonstrate the following:

(a) The existing laboratory or laboratories to be replaced are fully depreciated according to generally accepted accounting principles or demonstrates either of the following:

(i) The existing angiography x-ray equipment to be replaced poses a threat to the safety of the patients.

(ii) The replacement angiography x-ray equipment offers technological improvements that enhance quality of care, increases efficiency, and reduces operating costs.

(b) The existing angiography x-ray equipment to be replaced will be removed from service on or before beginning operation of the replacement equipment.

(2) An applicant proposing to replace a cardiac catheterization service to a new site shall demonstrate the following:

(a) The proposed project is part of an application to replace the entire hospital.
(b) The applicant has performed the following during the most recent 12-month period preceding the date the application was submitted to the Department as applicable to the proposed project:
(i) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.
(ii) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.
(iii) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.
(iv) A minimum of 500 procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.
(v) A minimum of 750 procedure equivalents for a hospital in a metropolitan county with one laboratory.
(vi) A minimum of 1,000 procedure equivalents per cardiac catheterization laboratory for a hospital with two or more laboratories.
(c) The existing cardiac catheterization service has been in operation for at least 36 months as of the date the application has been submitted to the Department.

Section 5. Requirements to expand a cardiac catheterization service

Sec. 5. An applicant proposing to add a laboratory to an existing cardiac catheterization service shall demonstrate the following:

(1) The applicant has performed the following during the most recent 12-month period preceding the date the application was submitted to the Department as applicable to the proposed project:
(a) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.
(b) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.
(c) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.

(2) The applicant has performed a minimum of 1,400 procedure equivalents per existing and approved laboratories during the most recent 12-month period preceding the date the application was submitted to the Department.

Section 6. Requirements to acquire a cardiac catheterization service

Sec. 6. Acquiring a cardiac catheterization service and its laboratories means obtaining possession and control by contract, ownership, lease or other comparable arrangement or renewal of a lease for existing angiography x-ray equipment. An applicant proposing to acquire a cardiac catheterization service or renew a lease for equipment shall demonstrate the following as applicable to the proposed project:

(1) An applicant proposing to acquire a cardiac catheterization service shall demonstrate the following:
(a) The proposed project is part of an application to acquire the entire hospital.
(b) An application for the first acquisition of an existing cardiac catheterization service after February 27, 2012 shall not be required to be in compliance with the applicable volume requirements in subsection (c). The cardiac catheterization service shall be operating at the applicable volumes set forth in the project delivery requirements in the second 12 months of operation of the service by the applicant and annually thereafter.

(c) The applicant has performed the following during the most recent 12-month period preceding the date the application was submitted to the Department as applicable to the proposed project :

(i) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.

(ii) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.

(iii) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.

(iv) A minimum of 500 procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.

(v) A minimum of 750 procedure equivalents for a hospital in a metropolitan county with one laboratory.

(vi) A minimum of 1,000 procedure equivalents per cardiac catheterization laboratory for two or more laboratories.

(2) An applicant proposing to renew a lease for existing angiography x-ray equipment shall demonstrate the renewal of the lease is more cost effective than replacing the equipment.

Section 7. Requirements for a hybrid operating room/cardiac catheterization laboratory (OR/CCL)

Sec. 7. 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 cardiac catheterization 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) The applicant operates a therapeutic cardiac catheterization program which is in full compliance with section 4(2) of these standards.

(3) If the hybrid OR/CCL(s) represents an increase in the number of cardiac catheterization laboratories at the facility, the applicant is in compliance with Section 5 of these standards.

(4) If the hybrid OR/CCL(s) represents conversion of an existing cardiac catheterization laboratory(s), the applicant is in compliance with the provisions of Section 4, if applicable.

(5) The applicant meets the applicable requirements of the CON Review Standards for Surgical Services.

(6) 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.

(7) For each hybrid OR/CCL, a facility shall have 0.5 excluded from its inventory of cardiac catheterization laboratories for the purposes of computing the procedure equivalents per room. A facility will not be limited to the number of hybrid ORCCLs within a single licensed facility.

Section 8. **Requirement for medicaid participation**

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

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

Sec. 9. An applicant shall agree that, if approved, the cardiac catheterization service and all existing and approved laboratories 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) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory located within a hospital, and have within, or immediately available to the room, dedicated emergency equipment to manage cardiovascular emergencies.

(b) The service shall be staffed with sufficient medical, nursing, technical and other personnel to permit regular scheduled hours of operation and continuous 24-hour on-call availability.

(c) The medical staff and governing body shall receive and review at least annual reports describing the activities of the cardiac catheterization service including complication rates, morbidity and mortality, success rates and the number of procedures performed.

(d) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization procedures shall perform, as the primary operator, a minimum of 75 adult therapeutic cardiac catheterization procedures per year in the second 12 months after being credentialed to and annually thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization procedures performed by that physician in any combination of hospitals.

(e) Each physician credentialed by a hospital to perform pediatric diagnostic cardiac catheterizations shall perform, as the primary operator, a minimum of 50 pediatric diagnostic cardiac catheterization procedures per year in the second 12 months after being credentialed and annually thereafter. The annual case load for a physician means pediatric diagnostic cardiac catheterization procedures performed by that physician in any combination of hospitals

(f) Each physician credentialed by a hospital to perform pediatric therapeutic cardiac catheterizations shall perform, as a primary operator, a minimum of 25 pediatric therapeutic cardiac catheterizations per year in the second 12 months after being credentialed and annually thereafter. The annual case load for a physician means pediatric therapeutic cardiac catheterization procedures performed by that physician in any combination of hospitals

(g) An adult diagnostic cardiac catheterization service shall have a minimum of two appropriately trained physicians on its active hospital staff. The Department may accept other evidence or shall consider it appropriate training if the staff physicians:

(i) are trained consistent with the recommendations of the American College of Cardiology;

(ii) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and

(iii) have each performed a minimum of 100 adult diagnostic cardiac catheterizations in the preceding 12 months.

(h) An adult therapeutic cardiac catheterization service shall have a minimum of two appropriately trained physicians on its active hospital staff. The Department may accept other evidence or shall consider it appropriate training if the staff physicians:

(i) are trained consistent with the recommendations of the American College of Cardiology;

(ii) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and

(iii) have each performed a minimum of 75 adult therapeutic cardiac catheterization procedures in the preceding 12 months.

(i) A pediatric cardiac catheterization service shall have an appropriately trained physician on its active hospital staff. The Department may accept other evidence or shall consider it appropriate training if the staff physician:

(i) is board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;

(ii) is credentialed by the hospital to perform pediatric cardiac catheterizations; and

(iii) has trained consistently with the recommendations of the American College of Cardiology.

(j) A cardiac catheterization service shall be directed by an appropriately trained physician. The Department shall consider appropriate training of the director if the physician is board certified in cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable. The director of an adult cardiac catheterization service shall have performed at least 200 catheterizations per year during each of the five preceding years. The Department may accept other evidence that the director is appropriately trained.

(k) A cardiac catheterization service shall be operated consistently with the recommendations of the American College of Cardiology.

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

(a) The service shall accept referrals for cardiac catheterization from all appropriately licensed practitioners.

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

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

(d) The operation of and referral of patients to the cardiac catheterization service shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.1621; MSA 14.15 (16221).

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

(a) the service shall be operating at or above the applicable volumes in the second 12 months of operation of the service, or an additional laboratory, and annually thereafter:

(i) 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.

(ii) 300 procedure equivalents in the category of adult therapeutic cardiac catheterization procedures.

(iii) 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.

(iv) 500 procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.

(v) 750 procedure equivalents for a hospital in a metropolitan county with one laboratory.

(vi) 1,000 procedure equivalents per cardiac catheterization laboratory for two or more laboratories.

(vii) 36 adult primary PCI cases for a primary PCI service.

(b) The hospital shall participate in a data collection network established and administered by the Department or its designee. Data may include, but is not limited to, annual budget and cost information, operating schedules, patient demographics, morbidity and mortality information, and payor. The Department may verify the data through on-site review of appropriate records.

(c) The hospital shall participate in a quality improvement data registry administered by the Department or its designee. The hospital shall submit summary reports as required by the Department. The hospital shall provide the required data in a format established by the Department or its designee. The hospital is liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. The hospital must become a member of the data registry upon initiation of the service and continue to participate annually thereafter for the life of that service.

(5) Compliance with the following primary PCI requirements, if applicable:

(a) The requirements set forth in Section 3(4).

(b) The hospital shall immediately report to the Department any changes in the interventional cardiologists who perform the primary PCI procedures.

(c) The hospital shall perform a minimum of 36 primary PCI procedures at the hospital in the preceding 12–month period of operation of the service and annually thereafter.

(d) The hospital shall maintain a 90-minute door-to-ballon time or less in at least 75% of the primary PCI sessions.

(e) The hospital shall participate in a data registry, administered by the Department or its designee. The Department or its designee shall require that the applicant submit data on all consecutive cases of primary PCI as is necessary to comprehensively assess and provide comparative analyses of case

selection, processes and outcome of care, and trend in efficiency. The applicant shall provide the required data in a format established by the Department or its designee. The applicant shall be liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality.

Section 10. Methodology for computing cardiac catheterization equivalents

Sec. 10. The following shall be used in calculating procedure equivalents and evaluating utilization of a cardiac catheterization service and its laboratories:

Procedure Type	Procedure equivalent	
	Adult	**Pediatric**
Diagnostic cardiac catheterization/peripheral sessions	1.5	2.7
Therapeutic cardiac catheterization/peripheral sessions	2.7	4.0
Complex percutaneous valvular sessions*	4.0	7.0
* Complex percutaneous valvular sessions includes, but is not limited to, procedures performed percutaneously or with surgical assistance to repair or replace aortic, mitral and pulmonary valves such as transcatheter aortic valvular implantation (Tavi) procedures. These sessions can only be performed at hospitals approved with open heart surgery services.		

Section 11. Documentation of projections

Sec. 11. An applicant required to project volumes shall demonstrate the following as applicable to the proposed project:

(1) The applicant shall specify how the volume projections were developed. Specification of the projections shall include a description of the data source(s) used and assessment of the accuracy of the data. The Department shall determine if the projections are reasonable.

(2) An applicant proposing to initiate a primary PCI service shall demonstrate and certify that the hospital treated or transferred 36 ST segment elevation AMI cases during the most recent 12-month period preceding the date the application was submitted to the Department. Cases may include thrombolytic eligible patients documented through pharmacy records showing the number of doses of thrombolytic therapy ordered and medical records of emergency transfers of AMI patients to an appropriate hospital for a primary PCI procedure.

Section 12. Comparative reviews; Effect on prior CON Review Standards

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 Cardiac Catheterization Services approved by the CON Commission on December 11, 2007 and effective on February 25, 2008.

APPENDIX A

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:
65 F.R., p. 82238 (December 27, 2000)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

APPENDIX B

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

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
426.7	ANOMALOUS ATRIOVENTRICULAR EXCITATION	I45.6	PRE-EXCITATION SYNDROME
427	CARDIAC DYSRYTHMIAS	I47.0-I47.9	PAROXYSMAL TACHYCARDIA
		I48.0-I48.92	ATRIAL FIBRILLATION AND FLUTTER
		I49.01-I49.9	OTHER CARDIAC ARRHYTHMIAS
		R00.1	BRADYCARDIA, UNSPECIFIED
745.0 through 747.99	BULBUS CORDIS ANOMALIES AND ANOMALIES OF CARDIAC SEPTAL CLOSURE, OTHER CONGENITAL ANOMALIES OF HEART, AND OTHER CONGENITAL ANOMALIES OF CIRCULATORY SYSTEM	P29.3	PERSISTENT FETAL CIRCULATION
		Q20.0-Q28.9	CONGENITAL MALFORMATIONS OF THE CIRCULATORY SYSTEM

"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.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR HOSPITAL BEDS

(By authority conferred on the CON Commission by sections 22215 and 22217 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 333.22217, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval under Part 222 of the Code that involve (a) beginning operation of a new hospital or (b) replacing beds in a hospital or physically relocating hospital beds from one licensed site to another geographic location or (c) increasing licensed beds in a hospital licensed under Part 215 or (d) acquiring a hospital . Pursuant to Part 222 of the Code, a hospital licensed under Part 215 is a covered health facility. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

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

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

(4) An increase in hospital beds certified for long-term care is a change in bed capacity for purposes of Part 222 of the Code and shall be subject to and reviewed under the CON Review Standards for Long-Term-Care Services.

Section 2. Definitions

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

(a) "Acquiring a hospital" means the issuance of a new hospital license as the result of the acquisition (including purchase, lease, donation, or other comparable arrangements) of a licensed and operating hospital and which does not involve a change in bed capacity.

(b) "Adjusted patient days" means the number of patient days when calculated as follows:

(i) Combine all pediatric patient days of care and obstetrics patient days of care provided during the period of time under consideration and multiply that number by 1.1.

(ii) Add the number of non-pediatric and non-obstetric patient days of care, excluding psychiatric patient days, provided during the same period of time to the product obtained in (i) above. This is the number of adjusted patient days for the applicable period.

(c) "Alcohol and substance abuse hospital" means a licensed hospital within a long-term (acute) care (LTAC) hospital that exclusively provides inpatient medical detoxification and medical stabilization and related outpatient services for persons who have a primary diagnosis of substance dependence covered by DRGs 433 - 437.

(d) "Average adjusted occupancy rate" shall be calculated as follows:

(i) Calculate the number of adjusted patient days during the most recent, consecutive 36-month period, as of the date of the application, for which verifiable data are available to the Department.

(ii) Calculate the total licensed bed days for the same 36-month period as in (i) above by multiplying the total licensed beds by the number of days they were licensed.

(iii) Divide the number of adjusted patient days calculated in (i) above by the total licensed bed days calculated in (ii) above, then multiply the result by 100.

(d) "Base year" means the most recent year that final MIDB data is available to the Department unless a different year is determined to be more appropriate by the Commission.

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

(f) "Close a hospital" means an applicant will demonstrate to the satisfaction of the Department that a hospital licensed under Part 215, and whose licensed capacity for the most recent 24 months prior to submission of the application was at least 80 percent for acute care beds, will close and surrender its acute care hospital license upon completion of the proposed project.

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

(h) "Common ownership or control" means a hospital that is owned by, is under common control of, or has a common parent as the applicant hospital.

(i) "Compare group" means the applications that have been grouped for the same type of project in the same hospital group and are being reviewed comparatively in accordance with the CON rules.

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

(k) "Department inventory of beds" means the current list maintained for each hospital group on a continuing basis by the Department of (i) licensed hospital beds and (ii) hospital beds approved by a valid CON issued under either Part 221 or Part 222 of the Code that are not yet licensed. The term does not include hospital beds certified for long-term-care in hospital long-term care units.

(l) "Disproportionate share hospital payments" means the most recent payments to hospitals in the special pool for non-state government-owned or operated hospitals to assure funding for costs incurred by public facilities providing inpatient hospital services which serve a disproportionate number of low-income patients with special needs as calculated by the Medical Services Administration within the Department.

(m) "Excluded hospitals" means hospitals in the following categories:

(i) Critical access hospitals designated by CMS pursuant to 42 CFR 485.606

(ii) Hospitals located in rural or micropolitan statistical area counties

(iii) LTAC hospitals

(iv) Sole community hospitals designated by CMS pursuant to 42 CFR 412.92

(v) Hospitals with 25 or fewer licensed beds

(n) "Existing hospital beds" means, for a specific hospital group, the total of all of the following: (i) hospital beds licensed by the Department of Licensing and Regulatory Affairs or its successor; (ii) hospital beds with valid CON approval but not yet licensed; (iii) proposed hospital beds under appeal from a final decision of the Department; and (iv) proposed hospital beds that are part of a completed application under Part 222 (other than the application under review) for which a proposed decision has been issued and which is pending final Department decision.

(o) "Gross hospital revenues" means the hospital's revenues as stated on the most recent Medicare and Michigan Medicaid forms filed with the Medical Services Administration within the Department.

(p) "Health service area" OR "HSA" means the groups of counties listed in Appendix A.

(q) "Hospital bed" means a bed within the licensed bed complement at a licensed site of a hospital licensed under Part 215 of the Code, excluding (i) hospital beds certified for long-term care as defined in Section 20106(6) of the Code and (ii) unlicensed newborn bassinets.

(r) "Hospital" means a hospital as defined in Section 20106(5) of the Code being Section 333.20106(5) of the Michigan Compiled Laws and licensed under Part 215 of the Code. The term does not include a hospital or hospital unit licensed or operated by the Department of Mental Health.

(s) "Hospital group" means a cluster or grouping of hospitals based on geographic proximity and hospital utilization patterns. The list of hospital groups and the hospitals assigned to each hospital group will be posted on the State OF Michigan CON web site and will be updated pursuant to Section 3.

(t) "Hospital long-term-care unit" or "HLTCU" means a nursing care unit, owned or operated by and as part of a hospital, licensed by the Department, and providing organized nursing care and medical treatment to 7 or more unrelated individuals suffering or recovering from illness, injury, or infirmity.

(u) "Host hospital" means a licensed and operating hospital, which delicenses hospital beds, and which leases patient care space and other space within the physical plant of the host hospital, to allow an LTAC hospital, or alcohol and substance abuse hospital, to begin operation.

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

(w) "Limited access area" means those underserved areas with a patient day demand that meets or exceeds the state-wide average of patient days used per 50,000 residents in the base year and as identified in Appendix D. Limited access areas shall be redetermined when a new hospital has been approved or an existing hospital closes.

(x) "Long-term (acute) care hospital" or "LTAC hospital" means a hospital has been approved to participate in the Title XVIII (Medicare) program as a prospective payment system (PPS) exempt hospital in accordance with 42 CFR Part 412.

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

(z) "Medicaid volume" means the number of Medicaid recipients served at the hospital as stated on the most recent Medicare and Michigan Medicaid forms filed with the Medical Services Administration within the Department.

(aa) "Michigan Inpatient Data Base" or "MIDB" means the data base compiled by the Michigan Health and Hospital Association or successor organization. The data base consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.

(bb) "New beds in a hospital" means hospital beds that meet at least one of the following: (i) are not currently licensed as hospital beds, (ii) are currently licensed hospital beds at a licensed site in one hospital group which are proposed for relocation in a different hospital group as determined by the Department pursuant to Section 3 of these standards, (iii) are currently licensed hospital beds at a licensed site in one hospital group which are proposed for relocation to another geographic site which is in the same hospital group as determined by the Department, but which are not in the replacement zone, or (iv) are currently licensed hospital beds that are proposed to be licensed as part of a new hospital in accordance with Section 6(2) of these standards.

(cc) "New hospital" means one of the following: (i) the establishment of a new facility that shall be issued a new hospital license, (ii) for currently licensed beds, the establishment of a new licensed site that is not in the same hospital group as the currently licensed beds, (iii) currently licensed hospital beds at a licensed site in one hospital group which are proposed for relocation to another geographic site which is in the same hospital group as determined by the Department, but which are not in the replacement zone, or (iv) currently licensed hospital beds that are proposed to be licensed as part of a new hospital in accordance with section 6(2) of these standards.

(dd) "Obstetrics patient days of care" means inpatient days of care for patients in the applicant's Michigan Inpatient Data Base data ages 15 through 44 with drgs 370 through 375 (obstetrical discharges).

(ee) "Overbedded hospital group" means a hospital group in which the total number of existing hospital beds in that hospital group exceeds the hospital group needed hospital bed supply.

(ff) "Pediatric patient days of care" means inpatient days of care for patients in the applicant's Michigan Inpatient Data Base data ages 0 through 14 excluding normal newborns.

(gg) "Planning year" means five years beyond the base year, established by the CON Commission, for which hospital bed need is developed, unless a different year is determined to be more appropriate by the Commission.

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

(ii) "Relocate existing licensed hospital beds" for purposes of sections 6(3) and 8 of these standards, means a change in the location of existing hospital beds from the existing licensed hospital site to a different existing licensed hospital site within the same hospital group or HSA. This definition does not apply to projects involving replacement beds in a hospital governed by Section 7 of these standards.

(jj) "Remaining patient days of care" means total inpatient days of care in the applicant's Michigan Inpatient Data Base data minus obstetrics patient days of care and pediatric patient days of care.

(kk) "Replace beds" means a change in the location of the licensed hospital, or the replacement of a portion of the licensed beds at the same licensed site. The hospital beds will be in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, etc.) within the replacement zone.

(ll) "Replacement zone" means a proposed licensed site that is (i) in the same hospital group as the existing licensed site as determined by the Department in accord with Section 3 of these standards and (ii) on the same site, on a contiguous site, or on a site within 2 miles of the existing licensed site if the existing licensed site is located in a county with a population of 200,000 or more, or on a site within 5 miles of the existing licensed site if the existing licensed site is located in a county with a population of less than 200,000.

(mm) "Uncompensated care volume" means the hospital's uncompensated care volume as stated on the most recent Medicare and Michigan Medicaid forms filed with the Medical Services Administration within the Department.

(nn) "Underserved area" means those geographic areas not within 30 minutes drive time of an existing licensed acute care hospital with 24 hour/7 days a week emergency room services utilizing the most direct route using the lowest speed limits posted as defined by the Michigan Department of Transportation (MDOT).

(oo) "Use rate" means the number of days of inpatient care per 1,000 population during a one-year period.

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

Section 3. Hospital groups

Sec. 3. Each existing hospital is assigned to a hospital group pursuant to subsection (1).

(1) These hospital groups and the assignments of hospitals to hospital groups shall be updated by the Department every five years or at the direction of the Commission. The methodology described in "New Methodology for Defining Hospital Groups" by Paul l. Delamater, Ashton M. Shortridge, and Joseph P. Messina, 2011 shall be used as follows:

(a) For each hospital, calculate the patient day commitment index (%C – a mathematical computation where the numerator is the number of inpatient hospital days from a specific geographic area provided by a specified hospital and the denominator is the total number of patient days provided by the specified hospital using MIDB data) for all Michigan zip codes using the summed patient days from the most recent three years of MIDB data. Include only those zip codes found in each year of the most recent three years of MIDB data. Arrange observations in an origin-destination table such that each hospital is an origin (row) and each zip code is a destination (column) and include only hospitals with inpatient records in the MIDB.

(b) For each hospital, calculate the road distance to all other hospitals. Arrange observations in an origin-destination table such that each hospital is an origin (row) and each hospital is also a destination (column).

(c) Rescale the road distance origin-destination table by dividing every entry in the road distance origin-destination table by the maximum distance between any two hospitals.

(d) Append the road distance origin-destination table to the %C origin-destination table (by hospital) to create the input data matrix for the clustering algorithm.

(e) Group hospitals into clusters using the k-means clustering algorithm with initial cluster centers provided by a wards hierarchical clustering method. Iterate over all cluster solutions from 2 to the number of hospitals (*n*) minus 1.

(i) For each cluster solution, record the group membership of each hospital, the cluster center location for each of the clusters, the r^2 value for the overall cluster solution, the number of single hospital clusters, and the maximum number of hospitals in any cluster.

(ii) "k-means clustering algorithm" means a method for partitioning observations into a user-specified number of groups. It is a standard algorithm with a long history of use in academic and applied research. The approach identifies groups of observations such that the sum of squares from points to the assigned cluster centers is minimized, i.e., observations in a cluster are more similar to one another than they are to other clusters. Several k-means implementations have been proposed; the bed need methodology uses the widely-adopted Hartigan-Wong algorithm. Any clustering or data mining text will discuss k-

means; one example is B.S. Everitt, S. Landau, M. Leese, & D. Stahl (2011) Cluster Analysis, 5th Edition. Wiley, 346 p.

(iii) "Wards hierarchical clustering method" means a method for clustering observations into groups. This method uses a binary tree structure to sequentially group data observations into clusters, seeking to minimize overall within-group variance. In the bed need methodology, this method is used to identify the starting cluster locations for k-means. Any clustering text will discuss hierarchical cluster analyis, including Ward's method; one example is: G. Gan, C. Ma, & J. Wu (2007) Data Clustering: Theory, Algorithms, and Applications (Asa-Siam Series on Statistics and Applied Probability). Society for Industrial and Applied Mathematics (Siam), 466 p.

(f) Calculate the incremental F score (F_{inc}) for each cluster solution (i) between 3 and n-1 letting:

r^2_i = r^2 of solution i

r^2_{i-1} = r^2 of solution i-1

k_i = number of clusters in solution i

k_{i-1} = number of clusters in solution i-1

n = total number of hospitals

where: $$F_{inc,i} = \frac{\left(\frac{r_i^2 - r_{i-1}^2}{k_i - k_{i-1}}\right)}{\left(\frac{1 - r_i^2}{n - (k_i - 1)}\right)}$$

(g) Select candidate solutions by finding those with peak values in f_{inc} scores such that $f_{inc,\,i}$ is greater than both $f_{inc,\,i-1}$ and $f_{inc,\,i+1}$.

(h) Remove all candidate solutions in which the largest single cluster contains more than 20 hospitals.

(i) Identify the minimum number of single hospital clusters from the remaining candidate solutions. Remove all candidate solutions containing a greater number of single hospital clusters than the identified minimum.

(j) From the remaining candidate solutions, choose the solution with the largest number of clusters (k). This solution (k clusters) is the resulting number and configuration of the hospital groups.

(k) Rename hospital groups as follows:

(i) For each hospital group, identify the HSA in which the maximum number of hospitals are located. In case of a tie, use the HSA number that is lower.

(ii) For each hospital group, sum the number of current licensed hospital beds for all hospitals.

(iii) Order the groups from 1 to k by first sorting by HSA number, then sorting within each HSA by the sum of beds in each hospital group. The hospital group name is then created by appending number in which it is ordered to "hg" (e.g., hg1, hg2, … hg$k$).

(iv) Hospitals that do not have patient records in the MIDB - identified in subsection (1)(a) - are designated as "ng" for non-groupable hospitals.

(2) For an application involving a proposed new licensed site for a hospital (whether new or replacement), the proposed new licensed site shall be assigned to an existing hospital group utilizing the methodology described in "A Methodology for Defining Hospital Groups" by Paul L. Delamater, Ashton M. Shortridge, and Joseph P. Messina, 2011 as follows:

(a) Calculate the road distance from proposed new site (s) to all existing hospitals, resulting in a list of n observations (s_n).

(b) Rescale s_n by dividing each observation by the maximum road distance between any two hospitals identified in subsection (1)(c).

(c) For each hospital group, subset the cluster center location identified in subsection (1)(e)(i) to only the entries corresponding to the road distance between hospitals. For each hospital group, the result is a list of n observations that define each hospital group's central location in relative road distance.

(d) Calculate the distance ($d_{K,S}$) between the proposed new site and each existing hospital group

where: $$d_{k,s} = \sqrt{\left(HG_{k,1} - s_1\right)^2 + \left(HG_{k,2} - s_2\right)^2 + \left(HG_{k,3} - s_3\right)^2 + \ldots + \left(HG_{k,n} - s_n\right)^2}$$

(e) Assign the proposed new site to the closest hospital group (HG*k*) by selecting the minimum value of $d_{k,s}$.

(f) If there is only a single applicant, then the assignment procedure is complete. If there are additional applicants, then steps (a) – (e) must be repeated until all applicants have been assigned to an existing hospital group.

(3) The Department shall amend the hospital groups to reflect: (a) approved new licensed site(s) assigned to a specific hospital group; (b) hospital closures; and (c) licensure action(s) as appropriate.

(4) As directed by the Commission, new hospital group assignments established according to subsection (1) shall supersede the previous subarea/hospital group assignments and shall be posted on the State of Michigan CON web site effective on the date determined by the Commission.

Section 4. Determination of the needed hospital bed supply

Sec. 4. (1) The determination of the needed hospital bed supply for a hospital group for a planning year shall be made using the MIDB and the methodology detailed in "New Methodology for Determining Needed Hospital Bed Supply" by Paul L. Delamater, Ashton M. Shortridge, and Joseph P. Messina, 2011 as follows:

(a) All hospital discharges for normal newborns (DRG 391 prior to 2008, DRG 795 thereafter) and psychiatric patients (ICD-9-CM codes 290 through 319, SEE APPENDIX E FOR ICD-10-CM CODES, as a principal diagnosis) will be excluded.

(b) For each county, compile the monthly patient days used by county residents for the previous five years (base year plus previous four years). Compile the monthly patient days used by non-Michigan residents in Michigan hospitals for the previous five years as an "out-of-state" unit. The out-of-state patient days unit is considered an additional county thereafter. Patient days are to be assigned to the month in which the patient was discharged. For patient records with an unknown county of residence, assign patient days to the county of the hospital where the patient received service.

(c) For each county, calculate the monthly patient days for all months in the planning year. For each county, construct an ordinary least squares linear regression model using monthly patient days as the dependent variable and months (1-60) as the independent variable. If the linear regression model is significant at a 90% confidence level (F-score, two tailed *p* value $\leq$ 0.1), predict patient days for months 109-120 using the model coefficients. If the linear regression model is not significant at a 90% confidence level (F-score, two tailed *p* value > 0.1), calculate the predicted monthly patient day demand in the planning year by finding the monthly average of the three previous years (months 25-60).

(d) For each county, calculate the predicted yearly patient day demand in the planning year. For counties with a significant regression model, sum the monthly predicted patient days for the planning year. For counties with a non-significant regression model, multiply the three year monthly average by 12.

(e) For each county, calculate the base year patient day commitment index (%c) to each hospital group. Specifically, divide the base year patient days from each county to each hospital group by the total number of base year patient days from each county.

(f) For each county, allocate the planning year patient days to the hospital groups by multiplying the planning year patient days by the %c to each hospital group from subsection (e).

(g) For each hospital group, sum the planning year patient days allocated from each county.

(h) For each hospital group, calculate the average daily census (ADC) for the planning year by dividing the planning year patient days by 365. Round each ADC value up to the nearest whole number.

(i) For each hospital group, select the appropriate occupancy rate from the occupancy table in Appendix C.

(j) For each hospital group, calculate the planning year bed need by dividing the planning year ADC by the appropriate occupancy rate. Round each bed need value up to the nearest whole number.

(2) The determination of the needed hospital bed supply for a limited access area shall be made using the MIDB and the methodology detailed in "A Methodology for Determining Needed Hospital Bed Supply" by Paul L. Delamater, Ashton M. Shortridge, And Joesph P. Messina, 2011 as follows:

(a) All hospital discharges for normal newborns (DRG 391 prior to 2008, DRG 795 thereafter) and psychiatric patients (ICD-9-CM codes 290 through 319, SEE APPENDIX E FOR ICD-10-CM CODES, as a principal diagnosis) will be excluded.

(b) Calculate the average patient day use rate of Michigan residents. Sum total patient days of Michigan residents in the base year and divide by estimated base year population for the state (population data available from US Census Bureau).

(c) Calculate the minimum number of patient days for designation of a limited access area by multiplying the average patient day use rate by 50,000. Round up to the nearest whole number.

(d) Follow steps outlined in Section 4(1)(b) – (d) to predict planning year patient days for each underserved area. Round up to the nearest whole number. The patient days for each underserved area are defined as the sum of the zip codes corresponding to each underserved area.

(e) For each underserved area, compare the planning year patient days to the minimum number of patient days for designation of a limited access area calculated in (c). Any underserved area with a planning year patient day demand greater than or equal to the minimum is designated as a limited access area.

(f) For each limited access area, calculate the planning year bed need using the steps outlined in Section 4(1)(h) – (j). For these steps, use the planning year patient days for each limited access area.

Section 5. Bed Need

Sec. 5. (1) The bed-need numbers shall apply to projects subject to review under these standards, except where a specific CON review standard states otherwise.

(2) The Department shall re-calculate the acute care bed need methodology in Section 4 every two years, or as directed by the Commission.

(3) The Commission shall designate the base year and the future planning year which shall be utilized in applying the methodology pursuant to subsection (2).

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

(5) New bed-need numbers established by subsections (2) and (3) shall supersede PREVIOUS bed-need numbers and shall be posted on the State Of Michigan CON web site as part of the hospital bed inventory.

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

Section 6. Requirements for approval -- new beds in a hospital

Sec. 6. (1) An applicant proposing new beds in a hospital, except an applicant meeting the requirements of subsection 2, 3, 4, or 5 shall demonstrate that it meets all of the following:

(a) The new beds in a hospital shall result in a hospital of at least 200 beds in a metropolitan statistical area county or 25 beds in a rural or micropolitan statistical area county. This subsection may be waived by the Department if the Department determines, in its sole discretion, that a smaller hospital is necessary or appropriate to assure access to health-care services.

(b) The total number of existing hospital beds in the hospital group to which the new beds will be assigned does not currently exceed the needed hospital bed supply. The Department shall determine the hospital group to which the beds will be assigned in accord with Section 3 of these standards.

(c) Approval of the proposed new beds in a hospital shall not result in the total number of existing hospital beds, in the hospital group to which the new beds will be assigned, exceeding the needed hospital bed supply. The Department shall determine the hospital group to which the beds will be assigned in accord with Section 3 of these standards.

(2) An applicant proposing to begin operation as a new LTAC hospital 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 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 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 hospital within the 12 or 18-month period, then the CON granted pursuant to this section shall expire automatically.

(b) The patient care space and other space to establish the new hospital is being obtained through a lease arrangement and renewal of a lease between the applicant and the host hospital. The initial, renewed, or any subsequent lease shall specify at least all of the following:

(i) That the host hospital shall delicense the same number of hospital beds proposed by the applicant for licensure in the new hospital or any subsequent application to add additional beds.

(ii) That the proposed new beds shall be for use in space currently licensed as part of the host hospital.

(iii) That upon non-renewal and/or termination of the lease, upon termination of the license issued under Part 215 of the act to the applicant for the new hospital, or upon noncompliance with the project delivery requirements or any other applicable requirements of these standards, the beds licensed as part of the new hospital must be disposed of by one of the following means:

(A) Relicensure of the beds to the host hospital. The host hospital must obtain a CON to acquire the LTAC hospital. In the event that the host hospital applies for a CON to acquire the LTAC hospital [including the beds leased by the host hospital to the LTAC hospital] within six months following the termination of the lease with the LTAC 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 hospital to the host hospital's medical/surgical licensed capacity and the application meets all other applicable project delivery requirements. The beds must be used for general medical/surgical purposes. Such an application shall not be subject to comparative review and shall be processed under the procedures for non-substantive review (as this will not be considered an increase in the number of beds originally licensed to the applicant at the host hospital);

(B) Delicensure of the hospital beds; or

(C) Acquisition by another entity that obtains a CON to acquire the new hospital in its entirety and that entity must meet and shall stipulate to the requirements specified in Section 6(2).

(c) The applicant or the current licensee of the new hospital shall not apply, initially or subsequently, for CON approval to initiate any other CON covered clinical services; provided, however, that this section is not intended, and shall not be construed in a manner which would prevent the licensee from contracting and/or billing for medically necessary covered clinical services required by its patients under arrangements with its host hospital or any other CON approved provider of covered clinical services.

(d) The new licensed hospital shall remain within the host hospital.

(e) The new hospital shall be assigned to the same hospital group as the host hospital.

(f) The proposed project to begin operation of a new hospital, under this subsection, shall constitute a change in bed capacity under Section 1(2) of these standards.

(g) The lease will not result in an increase in the number of licensed hospital beds in the hospital group.

(h) Applications proposing a new hospital under this subsection shall not be subject to comparative review.

(3) An applicant proposing to add new hospital beds, as the receiving licensed hospital under Section 8, shall demonstrate that it meets all of the requirements of this subsection and shall not be required to be in compliance with the needed hospital bed supply if the application meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.

(a) The approval of the proposed new hospital beds shall not result in an increase in the number of licensed hospital beds as follows:

(i) In the hospital group pursuant to Section 8(2)(a), or
(ii) in the HSA pursuant to Section 8(2)(b).

(b) Where the source hospital was subject to Section 8(3)(b), the receiving hospital shall have an average adjusted occupancy rate of 40 percent or above.

(c) Where the source hospital was subject to Section 8(3)(b), the addition of the proposed new hospital beds at the receiving hospital shall not exceed the number determined by the following calculation:

(i) As of the date of the application, calculate the adjusted patient days for the most recent, consecutive 36-month period where verifiable data is available to the Department, and divide by .40.

(ii) Divide the result of subsection (i) by 1095 (or 1096, if the 36-month period includes a leap year) and round up to next whole number or 25, whichever is larger. This is the maximum number of beds that can be licensed at the receiving hospital.

(iii) Subtract the receiving hospital's total number of licensed beds and approved beds from the result of subsection (ii). This is the maximum number of beds that can be added to the receiving hospital.

(d) Where the source hospital was subject to Section 8(3)(b), the receiving hospital's average adjusted occupancy rate must not be less than 40 percent after the addition of the proposed new hospital beds.

(e) Subsection (3)(b), (c), and (d) shall not apply to excluded hospitals.

(f) The proposed project to add new hospital beds, under this subsection, shall constitute a change in bed capacity under Section 1(2) of these standards.

(g) Applicants proposing to add new hospital beds under this subsection shall not be subject to comparative review.

(4) An applicant may apply for the addition of new beds if all of the following subsections are met. Further, an applicant proposing new beds at an existing licensed hospital site shall not be required to be in compliance with the needed hospital bed supply if the application meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.

(a) The beds are being added at the existing licensed hospital site.

(b) The hospital at the existing licensed hospital site has operated at an adjusted occupancy rate of 80 percent or above for the previous, consecutive 24 months based on its licensed and approved hospital bed capacity. The adjusted occupancy rate shall be calculated as follows:

(i) Calculate the number of adjusted patient days during the most recent, consecutive 24-month period for which verifiable data are available to the Department.

(ii) Divide the number calculated in (i) above by the total possible patient days [licensed and approved hospital beds multiplied by 730 (or 731 if including a leap year)]. This is the adjusted occupancy rate.

(c) The number of beds that may be approved pursuant to this subsection shall be the number of beds necessary to reduce the adjusted occupancy rate for the hospital to 75 percent. The number of beds shall be calculated as follows:

(i) Divide the number of adjusted patient days calculated in subsection (b)(i) by .75 to determine licensed bed days at 75 percent occupancy.

(ii) Divide the result of step (i) by 730 (or 731 if including a leap year) and round the result up to the next whole number.

(iii) Subtract the number of licensed and approved hospital beds as documented on the "Department Inventory of Beds" from the result of step (ii) and round the result up to the next whole number to determine the maximum number of beds that may be approved pursuant to this subsection.

(d) A licensed acute care hospital that has relocated its beds, after the effective date of these standards, shall not be approved for hospital beds under this subsection for five years from the effective date of the relocation of beds.

(e) Applicants proposing to add new hospital beds under this subsection shall not be subject to comparative review.

(f) Applicants proposing to add new hospital beds under this subsection shall demonstrate to the Department that they have pursued a good faith effort to relocate acute care beds from other licensed acute care hospitals within the HSA. At the time an application is submitted to the Department, the

applicant shall demonstrate that contact was made by one certified mail return receipt for each organization contacted.

(5) An applicant proposing a new hospital in a limited access area shall not be required to be in compliance with the needed hospital bed supply if the application meets all other applicable CON review standards, agrees and assures to comply with all applicable project delivery requirements, and all of the following subsections are met.

(a) The proposed new hospital, unless a critical access hospital, shall have 24 hour/7 days a week emergency services, obstetrical services, surgical services, and licensed acute care beds.

(b) The Department shall assign the proposed new hospital to an existing hospital group based on the current market use patterns of existing hospital groups.

(c) Approval of the proposed new beds in a hospital in a limited access area shall not exceed the bed need for the limited access area as determined by the bed need methodology in Section 4 and as set forth in Appendix D.

(d) The new beds in a hospital in a limited access area shall result in a hospital of at least 100 beds in a metropolitan statistical area county or 50 beds in a rural or micropolitan statistical area county. If the bed need for a limited access area, as shown in Appendix D, is less, then that will be the minimum number of beds for a new hospital under this provision. If an applicant for new beds in a hospital under this provision simultaneously applies for status as a critical access hospital, the minimum hospital size shall be that number allowed under state/federal critical access hospital designation.

(e) Applicants proposing to create a new hospital under this subsection shall not be approved, for a period of five years after beginning operation of the facility, of the following covered clinical services: (i) open heart surgery, (ii) therapeutic cardiac catheterization, (iii) fixed positron emission tomography (PET) services, (iv) all transplant services, (v) neonatal intensive care services/beds, and (vi) fixed urinary extracorporeal shock wave lithotripsy (UESWL) services.

(f) Applicants proposing to add new hospital beds under this subsection shall be prohibited from relocating the new hospital beds for a period of 10 years after beginning operation of the facility.

(g) An applicant proposing to add a new hospital pursuant to this subsection shall locate the new hospital as follows:

(i) In a metropolitan statistical area county, an applicant proposing to add a new hospital pursuant to this subsection shall locate the new hospital within the limited access area and serve a population of 50,000 or more inside the limited access area and within 30 minutes drive time from the proposed new hospital.

(ii) In a rural or micropolitan statistical area county, an applicant proposing to add a new hospital pursuant to this subsection shall locate the new hospital within the limited access area and serve a population of 50,000 or more inside the limited access area and within 60 minutes drive time from the proposed new hospital.

Section 7. Requirements for approval to replace beds

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

(2) The applicant shall specify whether the proposed project is to replace the licensed hospital to a new site or to replace a portion of the licensed beds at the existing licensed site.

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

(4) The applicant shall comply with the following requirements, as applicable:

(a) The applicant's hospital shall have an average adjusted occupancy rate of 40 percent or above.

(b) If the applicant hospital does not have an average adjusted occupancy rate of 40 percent or above, then the applicant hospital shall reduce the appropriate number of licensed beds to achieve an average adjusted occupancy rate of 60 percent or above. The applicant hospital shall not exceed the number of beds calculated as follows:

(i) As of the date of the application, calculate the number of adjusted patient days during the most recent, consecutive 36-month period where verifiable data is available to the Department, and divide by .60.

(ii) Divide the result of subsection (i) above by 1095 (or 1096 if the 36-month period includes a leap year) and round up to the next whole number or 25, whichever is larger. This is the maximum number of beds that can be licensed at the licensed hospital site after the replacement.

(c) Subsection (4)(a) and (b) shall not apply to excluded hospitals.

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

Section 8. Requirements for approval of an applicant proposing to relocate existing licensed hospital beds

Sec 8. (1) The proposed project to relocate beds, under this section, shall constitute a change in bed capacity under Section 1(3) of these standards.

(2) Any existing licensed acute care hospital (source hospital) may relocate all or a portion of its beds to another existing licensed acute care hospital as follows:

(a) The licensed acute care hospitals are located within the same hospital group, or

(b) the licensed acute care hospitals are located within the same HSA if the receiving hospital meets the requirements of Section 6(4)(b) of these standards.

(3) The applicant shall comply with the following requirements, as applicable:

(a) The source hospital shall have an average adjusted occupancy rate of 40 percent or above.

(b) If the source hospital does not have an average adjusted occupancy rate of 40 percent or above, then the source hospital shall reduce the appropriate number of licensed beds to achieve an average adjusted occupancy rate of 60 percent or above upon completion of the relocation(s). The source hospital shall not exceed the number of beds calculated as follows:

(i) As of the date of the application, calculate the number of adjusted patient days during the most recent, consecutive 36-month period where verifiable data is available to the Department, and divide by .60.

(ii) Divide the result of subsection (i) by 1095 (or 1096 if the 36-month period includes a leap year) and round up to the next whole number or 25, whichever is larger. This is the maximum number of beds that can be licensed at the source hospital site after the relocation.

(c) Subsections (3)(a) and (b) shall not apply to excluded hospitals.

(4) A source hospital shall apply for multiple relocations on the same application date, and the applications can be combined to meet the criteria of (3)(b) above. A separate application shall be submitted for each proposed relocation.

(5) The hospital from which the beds are being relocated, and the hospital receiving the beds, shall not require any ownership relationship.

(6) The relocated beds shall be licensed to the receiving hospital and will be counted in the inventory for the applicable hospital group.

(7) The relocation of beds under this section shall not be subject to a mileage limitation.

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

Sec. 9. An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

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

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

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

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

(i) Not deny services to any individual based on ability to pay or source of payment.

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

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

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

(a) An applicant approved pursuant to Section 6(4) must achieve a minimum occupancy of 75 percent over the last 12-month period in the three years after the new beds are put into operation, and for each subsequent calendar year, or the number of new licensed beds shall be reduced to achieve a minimum of 75 percent average annual occupancy for the revised licensed bed complement.

(b) The applicant must submit documentation acceptable and reasonable to the Department, within 30 days after the completion of the 3-year period, to substantiate the occupancy rate for the last 12-month period after the new beds are put into operation and for each subsequent calendar year, within 30 days after the end of the year.

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

(d) The applicant shall participate and submit data to the Michigan Inpatient Data Base (MIDB). The data shall be submitted to the Department or its designee.

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

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

Section 10. Rural, micropolitan statistical area, and metropolitan statistical area Michigan counties

Sec. 10. Rural, micropolitan statistical area, and metropolitan statistical area Michigan counties, for purposes of these standards, are incorporated as part of these standards as Appendix B. The Department may amend Appendix B as appropriate to reflect changes by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget.

Section 11. Department inventory of beds

Sec. 11. The Department shall maintain and provide on request a listing of the Department inventory of beds for each hospital group.

Section 12. Effect on prior planning policies; comparative reviews

Sec. 12. (1) These CON review standards supersede and replace the CON standards for hospital beds approved by the CON Commission on December 9, 2008 and effective March 2, 2009.

(2) Projects reviewed under these standards shall be subject to comparative review except those projects meeting the requirements of Section 7 involving the replacement of beds in a hospital within the replacement zone and projects involving acquisition (including purchase, lease, donation or comparable arrangements) of a hospital.

Section 13. Additional requirements for applications included in comparative reviews

Sec. 13. (1) Except for those applications for limited access areas, any application for hospital beds, that is subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards shall be grouped and reviewed comparatively with other applications in accordance with the CON rules.

(2) Each application in a comparative review group shall be individually reviewed to determine whether the application is a qualifying project. If the Department determines that two or more competing applications are qualifying projects, it shall conduct a comparative review. The Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section 22225(1) of the Code, and which have the highest number of points when the results of subsection (3) are totaled. If two or more qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects that, when taken together, do not exceed the need in the order in which the applications were received by the Department based on the date and time stamp placed on the applications by the department in accordance with rule 325.9123.

(3)(a) A qualifying project will be awarded points based on the percentile ranking of the applicant's uncompensated care volume and as measured by percentage of gross hospital revenues as set forth in the following table. The applicant's uncompensated care volume will be the cumulative of all currently licensed Michigan hospitals under common ownership or control with the applicant that are located in the same health service area as the proposed hospital beds. If a hospital under common ownership or control with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero. The source document for the calculation shall be the most recent Cost Report filed with the Department for purposes of calculating disproportionate share hospital payments.

Percentile Ranking	Points Awarded
90.0 – 100	25 pts
80.0 – 89.9	20 pts
70.0 – 79.9	15 pts
60.0 – 69.9	10 pts
50.0 – 59.9	5 pts

Where an applicant proposes to close a hospital(s) as part of its application, data from the hospital(s) to be closed shall be excluded from this calculation.

(b) A qualifying project will be awarded points based on the health service area percentile rank of the applicant's Medicaid volume as measured by percentage of gross hospital revenues as set forth in the following table. For purposes of scoring, the applicant's Medicaid volume will be the cumulative of all currently licensed Michigan hospitals under common ownership or control with the applicant that are located in the same health service area as the proposed hospital beds. If a hospital under common

ownership or control with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero. The source document for the calculation shall be the most recent Cost Report filed with the department for purposes of calculating disproportionate share hospital payments.

percentile rank	points awarded
87.5 – 100	20 pts
75.0 – 87.4	15 pts
62.5 – 74.9	10 pts
50.0 – 61.9	5 pts
less than 50.0	0 pts

Where an applicant proposes to close a hospital(s) as part of its application, data from the hospital(s) to be closed shall be excluded from this calculation.

(c) A qualifying project shall be awarded points as set forth in the following table in accordance with its impact on inpatient capacity. If an applicant proposes to close a hospital(s), points shall only be awarded if (i) closure of that hospital(s) does not create a bed need in any hospital group as a result of its closing; (ii) the applicant stipulates that the hospital beds to be closed shall not be transferred to another location or facility; and (iii) the utilization (as defined by the average daily census over the previous 24-month period prior to the date that the application is submitted) of the hospital to be closed is at least equal to 50 percent of the size of the proposed hospital (as defined by the number of proposed new licensed beds).

Impact on Capacity	Points Awarded
Closure of hospital(s)	25 pts
Closure of hospital(s) which creates a bed need	-15 pts

(d) A qualifying project will be awarded points based on the percentage of the applicant's historical market share of inpatient discharges of the population in an area which will be defined as that area circumscribed by the proposed hospital locations defined by all of the applicants in the comparative review process under consideration. This area will include any zip code completely within the area as well as any zip code which touches, or is touched by, the lines that define the area included within the figure that is defined by the geometric area resulting from connecting the proposed locations. In the case of two locations or one location or if the exercise in geometric definition does not include at least ten zip codes, the market area will be defined by the zip codes within the county (or counties) that includes the proposed site (or sites). Market share used for the calculation shall be the cumulative market share of the population residing in the set of above-defined zip codes of all currently licensed Michigan hospitals under common ownership or control with the applicant**,** which are in the same health service area.

Percent	Points Awarded
% of market share	% of market share served x 30 (total pts. awarded)

The source for calculations under this criterion is the MIDB.

Section 14. Review standards for comparative review of a limited access area

Sec. 14. (1) Any application subject to comparative review, under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and reviewed comparatively with other applications in accordance with the CON rules.

(2) Each application in a comparative group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws and all other applicable requirements for approval in the Code and these standards. If the Department determines that two or more competing applications satisfy all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws, and which have the highest number of points when the results of subsection (3) are totaled. If two or more qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects, when taken together, that do not exceed the need, as defined in Section 22225(1) in the order in which the applications were received by the Department based on the date and time stamp placed on the application by the Department when the application is filed.

(3)(a) A qualifying project will be awarded points based on the percentile ranking of the applicant's uncompensated care volume as measured by percentage of gross hospital revenues as set forth in the following table. For purposes of scoring, the applicant's uncompensated care will be the cumulative of all currently licensed Michigan hospitals under common ownership or control with the applicant. The source document for the calculation shall be the most recent Cost Report submitted to MDCH for purposes of calculating disproportionate share hospital payments. If a hospital under common ownership or control with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero.

Percentile Ranking	Points Awarded
90.0 – 100	25 pts
80.0 – 89.9	20 pts
70.0 – 79.9	15 pts
60.0 – 69.9	10 pts
50.0 – 59.9	5 pts

Where an applicant proposes to close a hospital as part of its application, data from the closed hospital shall be excluded from this calculation.

(b) A qualifying project will be awarded points based on the statewide percentile rank of the applicant's Medicaid volume as measured by percentage of gross hospital revenues as set forth in the following table. For purposes of scoring, the applicant's Medicaid volume will be the cumulative of all currently licensed Michigan hospitals under common ownership or control with the applicant. The source documents for the calculation shall be the Cost Report submitted to MDCH for purposes of calculating disproportionate share hospital payments. If a hospital under common ownership or control with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero.

Percentile Rank	Points Awarded
87.5 – 100	20 pts
75.0 – 87.4	15 pts
62.5 – 74.9	10 pts
50.0 – 61.9	5 pts
Less than 50.0	0 pts

Where an applicant proposes to close a hospital as part of its application, data from the closed hospital shall be excluded from this calculation.

(c) A qualifying project shall be awarded points as set forth in the following table in accordance with its impact on inpatient capacity in the health service area of the proposed hospital site.

Impact on Capacity	Points Awarded
Closure of hospital(s)	15 pts
Move beds	0 pts
Adds beds (net)	-15 pts
or	
Closure of hospital(s) or delicensure of beds which creates a bed need	
or	
Closure of a hospital which creates a new Limited Access Area	

(d) A qualifying project will be awarded points based on the percentage of the applicant's market share of inpatient discharges of the population in the limited access area as set forth in the following table. Market share used for the calculation shall be the cumulative market share of Michigan hospitals under common ownership or control with the applicant.

Percent	Points Awarded
% of market share	% of market share served x 15 (total pts awarded)

The source for calculations under this criterion is the MIDB.

(e) A qualifying project will be awarded points based on the percentage of the limited access area's population within a 30 minute travel time of the proposed hospital site if in a metropolitan statistical area county, or within 60 minutes travel time if in a rural or micropolitan statistical area county as set forth in the following table.

Percent	Points Awarded
% of population within 30 (or 60) minute travel time of proposed site	% of population covered x 15 (total pts awarded)

(f) All applicants will be ranked in order according to their total project costs as stated in the CON application divided by its proposed number of beds in accordance with the following table.

Cost Per Bed	Points Awarded
Lowest cost	10 pts
2nd Lowest cost	5 pts
All other applicants	0 pts

Section 15. Requirements for approval -- acquisition of a hospital

Sec. 15. (1) An applicant proposing to acquire a hospital shall not be required to be in compliance with the needed hospital bed supply for the hospital group in which the hospital subject to the proposed acquisition is assigned if the applicant demonstrates that all of the following are met:

(a) the acquisition will not result in a change in bed capacity,

(b) the licensed site does not change as a result of the acquisition,

(c) the project is limited solely to the acquisition of a hospital with a valid license, and

(d) if the application is to acquire a hospital, which was proposed in a prior application to be established as an LTAC hospital and which received CON approval, the applicant also must meet the

requirements of Section 6(2). Those hospitals that received such prior approval are so identified on the Department inventory of beds.

(2) The applicant shall comply with the following requirements, as applicable:

(a) The existing licensed hospital shall have an average adjusted occupancy rate of 40 percent or above.

(b) If the existing licensed hospital does not have an average adjusted occupancy rate of 40 percent or above, the applicant shall agree to all of the following:

(i) The hospital to be acquired will achieve an annual adjusted occupancy of at least 40% during any consecutive 12-month period by the end of the third year of operation after completion of the acquisition. Annual adjusted occupancy shall be calculated as follows:

(a) Calculate the number of adjusted patient days during the most recent, consecutive 12-month period for which verifiable data is available to the Department.

(b) Divide the number of adjusted patient days calculated in (a) above by 365 (or 366 if a leap year).

(c) If the hospital to be acquired does not achieve an annual adjusted occupancy of at least 40 percent, as calculated in (b) above, during any consecutive 12-month period by the end of the third year of operation after completion of the acquisition, the applicant shall relinquish sufficient beds at the existing hospital to raise its adjusted occupancy to 60 percent. The revised number of licensed beds at the hospital shall be calculated as follows:

(i) Calculate the number of adjusted patient days during the most recent, consecutive 12-month period where verifiable data is available to the Department, and divide by .60.

(ii) Divide the result of subsection (i) above by 365 (or 366 if the 12-month period includes a leap year) and round up to the next whole number or 25, whichever is larger. This is the maximum number of beds that can be licensed at the existing licensed hospital site after acquisition.

(d) Subsection (2) shall not apply to excluded hospitals.

Section 16. Requirements for approval – all applicants

Sec. 16. (1) An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

(2) The applicant certifies all outstanding debt obligations owed to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP) have been paid in full.

(3) The applicant certifies that the health facility for the proposed project has not been cited for a state or federal code deficiency within the 12 months prior to the submission of the application. If a state code deficiency has been issued, the applicant shall certify that a plan of correction for cited state deficiencies at the health facility has been submitted and approved by the Bureau of Health Systems within the Department of Licensing and Regulatory Affairs. If a federal code deficiency has been issued, the applicant shall certify that a plan of correction for cited federal deficiencies at the health facility has been submitted and approved by the Centers for Medicare and Medicaid Services. If code deficiencies include any unresolved deficiencies still outstanding with the Department of Licensing and Regulatory Affairs or the Centers for Medicare and Medicaid Services that are the basis for the denial, suspension, or revocation of an applicant's health facility license, poses an immediate jeopardy to the health and safety of patients, or meets a federal conditional deficiency level, the proposed project cannot be approved without approval from the Bureau of Health Systems or, if applicable, the Centers for Medicare and Medicaid Services.

APPENDIX A

Counties assigned to each health service area are as follows:

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

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

OCCUPANCY RATE TABLE

HOSPITAL GROUP PROJECTED BED ADC			ADJUSTED BED RANGE	
ADC _LOW	ADC_HIGH	OCCUPANCY RATE	BEDS_LOW	BED S_HIGH
30	31	60%	50	52
32	35	61%	53	58
36	39	62%	59	53
40	45	63%	64	72
46	50	64%	72	79
51	58	65%	79	90
59	67	66%	90	102
68	77	67%	102	115
78	88	68%	115	130
89	101	69%	129	147
102	117	70%	146	168
118	134	71%	167	189
135	154	72%	188	214
155	176	73%	213	242
177	204	74%	240	276
205	258	75%	274	344
259	327	76%	341	431
328	424	77%	426	551
425	561	78%	545	720
562	760	79%	712	963
761	895	80%	952	1119

LIMITED ACCESS AREAS

Limited access areas and the hospital bed need, effective September 28, 2012, for each of those areas are identified below. The hospital bed need for limited access areas shall be changed by the Department in accordance with section 2(1)(w) of these standards, and this appendix shall be updated accordingly.

LIMITED ACCESS AREA	BED NEED	PREDICTED PATIENT DAYS
1 Upper Peninsula	255	68,551
2 East/Central Northern Lower Peninsula	143	35,754
3 West Northern Lower Peninsula	383	106,135
4 East Southern Lower Peninsula	131	32,720

Sources:

1) Michigan State University
Department of Geography
2012 REPORT: Hospital Groups, Determination of Needed Hospital Bed Supply, and Limited Access Areas
August 22, 2012

2) Section 4 of these standards

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

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
290 THROUGH 319	PSYCHIATRIC PATIENTS	F01.50-F99	MENTAL, BEHAVIORAL, AND NEURODEVELOPMENTAL DISORDERS

"ICD-9-CM CODE" MEANS THE DISEASE CODES AND NOMENCLATURE FOUND IN THE **INTERNATIONAL CLASSIFICATION OF DISEASES - 9TH REVISION - CLINICAL MODIFICATION,** PREPARED BY THE COMMISSION ON PROFESSIONAL AND HOSPITAL ACTIVITIES FOR THE U.S. NATIONAL CENTER FOR HEALTH STATISTICS.

"ICD-10-CM CODE" MEANS THE DISEASE CODES AND NOMENCLATURE FOUND IN THE INTERNATIONAL CLASSIFICATION OF DISEASES - 10TH REVISION - CLINICAL MODIFICATION, NATIONAL CENTER FOR HEALTH STATISTICS.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR OPEN HEART SURGERY (OHS) SERVICES

(By the 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 of the initiation or acquisition of OHS services, and delivery of these services under Part 222 of the Code. Pursuant to Part 222 of the Code, OHS 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) “Adult OHS” means OHS offered and provided to individuals age 15 and older as defined in subsection (i).

(b) "Cardiac surgical team" means the designated specialists and support personnel who consistently work together in the performance of OHS.

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

(f) “Hospital” means a health facility licensed under Part 215 of the Code.

~~(g) "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.~~

(~~h~~g) " Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to 1396g and1396i to 1396u.

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

(j) "Open heart surgery" means any cardiac surgical procedure involving the heart and/or thoracic great vessels (excluding organ transplantation) that is intended to correct congenital and acquired cardiac and coronary artery disease and/or great vessels and often uses a heart-lung pump (pumps and oxygenates the blood) or its equivalent to perform the functions of circulation during surgery. These procedures may be performed off-pump (beating heart), although a heart-lung pump is still available during the procedure.

(k) “Open heart surgical case” means a single visit to an operating room during which one or more OHS procedures are performed. The list of OHS procedures shall be maintained by the Department.

(l) "OHS service" means a hospital program that is staffed with surgical teams and other support staff for the performance of open heart surgical procedures. An OHS service performs OHS procedures on an emergent, urgent and scheduled basis.

(m) "Pediatric OHS" means OHS offered and provided to infants and children age 14 and younger, and to other individuals with congenital heart disease as defined by the ICD-9-CM codes of 745.0 through 747.99 (SEE APPENDIX C FOR ICD-10-CM CODES).

(n) "Planning area" means the groups of counties shown in Section 10.

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

Section 3. Requirements to initiate OHS services

Sec. 3. (1) An applicant proposing to initiate either adult or pediatric OHS as a new service shall be a hospital and operating or approved to operate a diagnostic and therapeutic adult or pediatric cardiac catheterization service, respectively.

(2) A hospital proposing to initiate OHS as a new service shall have a written consulting agreement with a hospital which has an existing active OHS service performing a minimum of 400 open heart surgical cases per year for 3 consecutive years. The agreement must specify that the existing service shall, for the first 3 years of operation of the new service, provide the following services to the applicant hospital:

(a) Receive and make recommendations on the proposed design of surgical and support areas that may be required;

(b) Provide staff training recommendations for all personnel associated with the new proposed service;

(c) Provide recommendations on staffing needs for the proposed service; and

(d) 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: (i) Mortality rates, (ii) Complication rates, (iii) Success rates, and (iv) Infection rates.

(3) An applicant proposing to initiate adult OHS as a new service shall demonstrate 300 adult open heart surgical cases based on the methodology set forth in Section 8.

(4) An applicant proposing to initiate pediatric OHS as a new service shall demonstrate 100 pediatric open heart surgical cases based on the methodology set forth in Section 9.

Section 4. Requirements to acquire an existing open heart surgery service

Sec. 4. An applicant proposing to acquire a hospital that has been approved to perform OHS services may also acquire the existing OHS service if it can demonstrate that the proposed project meets all of the following:

(1) An application for the first acquisition of an existing OHS service after February 25, 2008 shall not be required to be in compliance with the applicable volume requirements on the date of acquisition. The OHS service shall be operating at the applicable volume requirements set forth in Section 7 of these standards in the second 12 months after the date the service is acquired, and annually thereafter.

(2) Except as provided for in subsection (1), an application for the acquisition of an existing OHS service after February 25, 2008 shall be required to be in compliance with the applicable volume requirements, as set forth in the project delivery requirements, on the date an application is submitted to the Department.

(3) The applicant agrees to operate the OHS service in accordance with all applicable project delivery requirements set forth in Section 7 of these standards.

Section 5. Requirements for Medicaid participation

Sec 5**.** 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 6. Requirements for MIDB data commitments

Sec. 6. In order to use MIDB data in support of an application for either adult or pediatric OHS services, an applicant shall demonstrate or agree, as applicable, to all of the following:

(1) A hospital(s) whose adult MIDB data is used in support of a CON application for adult OHS services shall not use any of its adult MIDB data in support of any other application for adult OHS services prior to 7 years after the initiation of the OHS service for which MIDB data were used to support. After the 7-year period, a hospital(s) may only commit its adult MIDB data in support of another application for adult OHS services if they have experienced an increase from the previously committed MIDB data. Only that additional increase in MIDB data can be committed to another applicant to initiate OHS services.

(2) A hospital(s) whose pediatric MIDB data is used in support of a CON application for pediatric OHS services shall not use any of its pediatric MIDB data in support of any other application for pediatric OHS services prior to 7 years after the initiation of the OHS service for which MIDB data were used to support. After the 7-year period, a hospital(s) may only commit its pediatric MIDB data in support of another application for pediatric OHS services if they have experienced an increase from the previously committed MIDB data. Only that additional increase in MIDB data can be committed to another applicant to initiate OHS services.

(3) The hospital(s) committing MIDB data does not currently operate an adult or pediatric OHS service or have a valid CON issued under Part 222 to operate an adult or pediatric OHS service.

(4) The hospital(s) committing MIDB data is located in the same planning area as the hospital to which MIDB data is being proposed to be committed.

(5) The hospital(s) committing MIDB data to a CON application has completed the departmental form(s) which (i) authorizes the Department to verify the MIDB data, (ii) agrees to pay all charges associated with verifying the MIDB data, and (iii) acknowledges and agrees that the commitment of the MIDB data is for the period of time specified in subsection (1) or (2), as applicable.

(6) The hospital(s) committing MIDB data to an application is regularly admitting patients as of the date the Director makes the final decision on that application, under Section 22231 of the Code, being Section 333.22231 of the Michigan Compiled Laws.

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

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

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) Each physician credentialed by the hospital to perform adult OHS cases, as the attending surgeon, shall perform a minimum of 50 adult OHS cases per year. The annual case load for a physician means adult OHS cases performed by that physician, as the attending surgeon, in any hospital or combination of hospitals.

(b) The service shall have the cardiac surgical team available on call for emergency cases 24 hours a day, 7 days a week.

(c) The applicant hospital shall participate with the Society of Thoracic Surgeons (STS) National Database and the Michigan Society of Thoracic and Cardiovascular Surgeons (MSTCVS) Quality Collaborative and Database or a designee of the Department that monitors quality and risk adjusted outcomes.

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

(a) The service shall accept referrals for OHS from all appropriately licensed practitioners.

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

(c) The applicant hospital shall not deny OHS services to any individual based on the ability to pay or source of payment.

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

(d) The operation of and referral of patients to the OHS services shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.1621; MSA 14.15 (16221).

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

(a) The OHS service shall be operating at an annual level of 150 adult open heart surgical cases or 100 pediatric open heart surgical cases, as applicable, as submitted to the STS Database, by the end of the third 12 full months of operation, and annually thereafter.

(b) The applicant hospital shall prepare and present to the medical staff and governing body reports describing activities in the OHS service including complication rates and other morbidity and mortality data.

(c) The applicant hospital 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, patient demographics, diagnostic, morbidity and mortality information, and the volume of care provided to patients from all payor sources. The applicant hospital shall provide the required data in a format established by the Department and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(d) The applicant hospital shall participate in a data registry administered by the Department or its designee as a means to measure quality and risk adjusted outcomes within OHS programs. The Department shall use the STS Composite Star Rating System which currently includes coronary artery bypass graft composite (CABG), aortic valve replacement composite, and plans to add additional cardiac surgical composites each year. The Department or its designee shall require that the applicant hospital submit a summary report as specified by the Department. The applicant hospital shall provide the required data in a format established by the Department or its designee. The applicant hospital shall be liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. The applicant hospital shall become a member of the data registry specified by the Department upon initiation of the service and continue to participate annually thereafter for the life of that service. The outcomes database must undergo statewide auditing.

(e) The applicant hospital shall utilize and report the STS Composite Star Rating System for all procedures as follows:

(i) If the program receives a one-star rating in any composite metric, they shall submit a report to the Department explaining the reason(s) for the unsatisfactory rating.

(ii) If the program receives two one-star ratings in a row in the same composite metric, they shall submit an action plan to the Department detailing specific actions to rectify the program deficiencies.

(iii) If the program receives two one-star ratings within the same composite metric, the program may have two years to obtain a minimum two-star rating within that composite metric. Upon receipt of a two-star or higher rating, the program may be considered in compliance.

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

(5) Nothing in this section prohibits the Department from taking compliance action under MCL 333.22247.

(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 8. Methodology for computing the number of adult open heart surgical cases

Sec. 8. (1) The weights for the adult principal and non-principal diagnoses tables found in Appendix A are calculated using the following methodology. For these two tables, only the MIDB data from licensed hospitals that have operational OHS programs in Michigan will be used. Using the hospitals' actual inpatient discharge data, as specified by the most recent MIDB data available to the Department, the discharges that were from patients aged 15 years and older shall be identified. These discharges shall be known as the "adult discharges."

(a) To calculate the weights for the principal diagnosis, the following steps shall be taken:

(i) For each diagnostic group in the principal weight table, the discharges having a primary diagnosis matching any diagnosis in the diagnostic group are identified. The number of discharges is counted.

(ii) For the discharges identified in subsection 8(1)(a)(i), any occurrence of an open heart procedure code will be considered as a single OHS case. For each diagnostic group, the number of OHS cases is counted.

(iii) The number of OHS cases for each diagnosis category identified in subsection 8(1)(a)(ii) will be divided by the number of discharges identified in subsection 8(1)(a)(i). This will be the weight for that diagnostic group. This number should show six decimal positions.

(iv) All discharges utilized for the computation of the principal weight table are to be removed from subsequent analyses.

(b) To calculate the weights for the non-principal diagnosis table, the following steps shall be taken, separately, in the sequence of the group order found in the non-principal diagnosis table:

(i) Each remaining discharge will be examined for any mention of the diagnostic codes from that group. If a match is found, that discharge is assigned to that diagnostic group and removed from subsequent analyses. The number of discharges in each diagnostic group is counted.

(ii) For each diagnostic group taken separately, in the sequence shown, any occurrence of an open heart procedure code for each discharge will be counted as a single OHS case. If a match is found, the discharge will be considered as an open heart surgical case for that diagnostic group and removed from subsequent analyses. The number of open heart surgical cases in each diagnostic group is counted.

(ii) The number of OHS cases for each non-principal diagnosis category identified in subsection 8(1)(b)(ii) will be divided by the number of discharges identified in subsection 8(1)(b)(i). This will result in the non-principal weight for that diagnostic group. This number should show six decimal positions.

(2) An applicant shall apply the methodology set forth in this section for computing the projected number of adult open heart surgical cases using both the principal and non-principal diagnosis tables. The following steps shall be taken in sequence:

(a) For each diagnostic group in the principal weight table in Appendix A, identify the corresponding number of discharges.

(b) Multiply the number of discharges for each diagnostic group by their respective group weight to obtain the projected number of OHS cases for that group. All discharges identified in subsection 8(2)(a) are removed from subsequent analysis.

(c) The non-principal weight table identifies the sequence that must be followed to count the discharges for the appropriate group. An applicant shall start with the first diagnostic group and shall count the number of discharges with any mention of a non-principal diagnosis corresponding to that specific diagnostic group. When a discharge that belongs in the specific non-principal diagnostic group is identified, it is assigned to that group. This discharge is then removed from the data before counting discharges for the next diagnostic group. The discharges counted for each group will be used only with the non-principal diagnosis weight table in Appendix A and will be entered into its respective diagnostic

group. Multiply the number of discharges for each diagnostic group by their respective group weight to obtain the projected number of OHS cases for that group.

(d) The total number of projected open heart cases is then calculated by summing the projected number of open heart cases from both principal and non-principal weight tables.

(3) The major ICD-9-CM groupings (SEE APPENDIX D FOR ICD-10-CM CODES) and Open Heart utilization weights in Appendix A are based on the work of the Bureau of Policy and Planning, Michigan Department of Community Health, utilizing the most current MIDB data available to the Department.

(a) The Department shall update the open heart utilization weights every 3 years, beginning with the year 2007, according to the methodology described in subsection (1) above, utilizing the most current MIDB data available to the Department.

(b) Updates to the utilization weights made pursuant to this subsection shall not require standard advisory committee action, a public hearing, or submittal of the standard to the legislature and governor in order to become effective.

(c) The Department shall notify the Commission when the updates are made and the effective date of the updated utilization weights.

(d) The updated open heart utilization weights established pursuant to this subsection shall supercede the weights shown in Appendix A and shall be included as an amended appendix to these standards.

(4) Each applicant shall provide access to verifiable hospital-specific data and documentation using a format established by the Department and a mutually agreed upon media.

Section 9. Methodology for computing the number of pediatric open heart surgical cases

Sec. 9. (1) The weights for the pediatric diagnosis table found in Appendix B are calculated using the following methodology. Only the MIDB data from licensed hospitals that have operational OHS programs in Michigan will be used.

(a) Using the hospitals' actual inpatient discharge data, as specified by the most recent MIDB data available to the Department, the discharges that were from patients of any age that have a diagnosis (any mention) of the ICD-9-CM codes (SEE APPENDIX E FOR ICD-10-CM CODES) listed in the "Congenital Anomalies" category in Appendix B shall be counted. Each identified record shall be counted only once so that no record is counted twice. An applicant shall remove these cases from subsequent analyses.

(b) For those discharges identified in subsection 9(1)(a), any occurrence of an open heart procedure code will be considered as a single OHS case. The number of open heart surgical cases is counted.

(c) The number of OHS cases for the "Congenital Anomalies" category identified in subsection 9(1)(b) will be divided by the number of discharges identified in subsection 9(1)(a). This will be the weight for the "Congenital Anomalies" diagnostic group. This number should show six decimal positions.

(d) Using the hospitals' remaining inpatient discharges, the discharges that were from patients aged 14 years and younger shall be identified. These discharges shall be known as the "pediatric discharges."

(e) Using the "pediatric discharges" identified in subsection 9(1)(d), the number of discharges that have a diagnosis (any mention) of the ICD-9-CM codes (SEE APPENDIX E FOR ICD-10-CM CODES) listed in the "All Other Heart Conditions" category in Appendix B shall be counted. Discharge records which do not have one or more of the "All Other Heart Conditions" codes listed in Appendix B shall not be used. Each identified record shall be counted only once so that no record is counted twice.

(f) For those discharges identified in subsection 9(1)(e), any occurrence of an open heart procedure code will be considered as a single OHS case. The number of open heart surgical cases is counted.

(g) The number of OHS cases for the "All Other Heart Conditions" category identified in subsection 9(1)(f) will be divided by the number of discharges identified in subsection 9(1)(e). This will be the weight for the "All Other Heart Conditions" diagnostic group. This number should show six decimal positions.

(2) An applicant shall apply the methodology set forth in this section for computing the projected number of pediatric open heart surgical cases. In applying discharge data in the methodology, each applicable inpatient record is used only once. This methodology shall utilize only those inpatient

discharges that have one or more of the cardiac diagnoses listed in Appendix B. In applying this methodology, the following steps shall be taken in sequence:

(a) Using a hospital's actual inpatient discharge data, as specified by the most recent MIDB data available to the Department, an applicant shall count the discharges that were from patients of any age that have a principal diagnosis or any of the first four non-principal diagnoses of the ICD-9-CM codes (SEE APPENDIX E FOR ICD-10-CM CODES) listed in the "Congenital Anomalies" category in Appendix B. Each identified record shall be counted only once so that no record is counted twice. An applicant shall remove these cases from the discharge data.

(b) Using a hospital's remaining inpatient discharges, an applicant shall identify the discharges that were from patients aged 14 years and younger. These discharges shall be known as the "pediatric discharges."

(c) Using the "pediatric discharges" identified in Subdivision (b), an applicant shall count the number of discharges with a principal diagnosis or any of the first four non-principal diagnoses of the ICD-9-CM codes (SEE APPENDIX E FOR ICD-10-CM CODES) listed in the "All Other Heart Conditions" category in Appendix B. Discharge records which do not have one or more of the “All Other Heart Conditions” codes listed in Appendix B shall not be used. Each identified record shall be counted only once so that no record is counted twice.

(d) An applicant shall multiply the count for the "Congenital" and "All Other Heart Conditions" categories by the corresponding Pediatric Open Heart Utilization Weight and add the products together to produce the number of pediatric open heart surgical cases for the applicant.

(3) The major ICD-9-CM groupings (SEE APPENDIX E FOR ICD-10-CM CODES) and Pediatric Open Heart Utilization Weights in Appendix B are based on the work of the Bureau of Policy and Planning, Michigan Department of Community Health, utilizing the most current MIDB data available to the Department.

(a) The Department shall update the open heart utilization weights every 3 years, beginning with the year 2007, according to the methodology described in subsection (1) above, utilizing the most current MIDB data available to the Department.

(b) Updates to the utilization weights made pursuant to this subsection shall not require standard advisory committee action, a public hearing, or submittal of the standard to the legislature and governor in order to become effective.

(c) The Department shall notify the Commission when the updates are made and the effective date of the updated utilization weights.

(d) The updated open heart utilization weights established pursuant to this subsection shall supercede the weights shown in Appendix B and shall be included as an amended appendix to these standards.

(4) Each applicant must provide access to verifiable hospital-specific data and documentation using a format established by the Department and in a mutually agreed upon media.

Section 10. Planning Areas

Sec. 10. Counties assigned to each planning area are as follows:

PLANNING 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

Section 11. Effect on prior planning policies; comparative reviews

Sec. 11. (1) These CON Review Standards supersede and replace the CON Review Standards for OHS Services approved by the CON Commission on ~~December 11, 2007~~SEPTEMBER 17, 2013 and effective on ~~February 25, 2008~~NOVEMBER 15, 2015.

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

Appendix A

DIAGNOSIS GROUPINGS FOR ADULT OPEN HEART SURGICAL CASES
PRINCIPAL DIAGNOSIS
(SEE APPENDIX D FOR ICD-10-CM CODES)

GROUP	MAJOR ICD-9-CM CODE GROUP	CATEGORY	ADULT OPEN HEART UTILIZATION WEIGHTS
A	394 – 397.9 421 – 421.9 424 – 424.99	Valves	.730737
B	441.01, 441.03 441.1, 441.2 441.6, 441.7	Aortic Aneurysm	.641457
C	745 – 747.99	Congenital Anomalies	.362101
D	414 – 414.99	Other Chronic Ischemic	.224163
E	410 – 410.99	Acute Myocardial Infarct	.101479
F	212.7 398 – 398.99 411 – 411.99 423 – 423.9 425 – 425.9 427 – 427.9 428 – 428.9 901 – 901.9 996.02, 996.03	All Other Heart Conditions	.013366

NON-PRINCIPAL DIAGNOSES

GROUP	MAJOR ICD-9-CM CODE GROUP	CATEGORY	ADULT OPEN HEART UTILIZATION WEIGHTS
A	745 – 747.99	Congenital Anomalies	.016876
B	441.01, 441.03 441.1, 441.2 441.6, 441.7	Aortic Aneurysm	.030120
C	410 – 410.99	Acute Myocardial Infarct	.012099
D	394 – 397.9 421 – 421.9 424 – 424.99	Valves	.007648
E	414 – 414.99	Other Chronic Ischemic	.001466

F	212.7 398 – 398.99 411 – 411.99 423 – 423.9 425 – 425.9 427 – 427.9 428 – 428.9 901 – 901.9 996.02, 996.03	All Other Heart Conditions	.001206

Source: Calculated based on the 2010 Michigan Inpatient Data Base

Appendix B

DIAGNOSIS GROUPINGS FOR PEDIATRIC OPEN HEART SURGICAL CASES
(SEE APPENDIX E FOR ICD-10-CM CODES)

MAJOR ICD-9-CM CODE GROUP	CATEGORY	PEDIATRIC OPEN HEART UTILIZATION WEIGHTS
745.0 – 747.99	Congenital Anomalies	.234512
164.1, 212.7 390 – 429.99 441.01, 441.03 441.1, 441.2 441.6, 441.7 785.51 786.5-786.59 901.0 – 901.9 996.02	All Other Heart Conditions	.018991

Source: Calculated based on the 2010 Michigan Inpatient Data Base

APPENDIX C

ICD-9-CM TO ICD-10-CM CODE TRANSLATION FOR CONGENITAL HEART DISEASE

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
745.0 THROUGH 747.99	CONGENITAL HEART DISEASE	P29.3	PERSISTENT FETAL CIRCULATION
		Q20.0-Q28.9	CONGENITAL MALFORMATIONS OF THE CIRCULATORY SYSTEM

"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.

APPENDIX D

ICD-9-CM TO ICD-10-CM CODE TRANSLATION FOR APPENDIX A

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
394 – 397.9	VALVES	I05.0-I08.9	RHEUMATIC VALVE DISEASES
		I09.0-I09.89	OTHER RHEUMATIC HEART DISEASES
421 – 421.9	VALVES	A01.02	TYPHOID FEVER WITH HEART INVOLVEMENT
		I33.0-I33.9	ACUTE AND SUBACUTE ENDOCARDITIS
		I39	ENDOCARDITIS AND HEART VALVE DISORDERS IN DISEASES CLASSIFIED ELSEWHERE
424 – 424.99	VALVES	A18.84	TUBERCULOSIS OF HEART
		I34.0-I37.9	NONRHEUMATIC VALVE DISORDERS
		I38	ENDOCARDITIS, VALVE UNSPECIFIED
		I39	ENDOCARDITIS AND HEART VALVE DISORDERS IN DISEASES CLASSIFIED ELSEWHERE
		I42.0-I43	CARDIOMYOPATHIES
		M32.11	ENDOCARDITIS IN SYSTEMIC LUPUS ERYTHEMATOSUS
441.01, 441.03	AORTIC ANEURYSM	I71.01, I71.03	DISSECTION OF THORACIC/THORACOABDOMINAL AORTA
441.1, 441.2	AORTIC ANEURYSM	I71.1, I71.2	THORACIC AORTIC ANEURYSM, RUPTURED/WITHOUT RUPTURE
441.6, 441.7	AORTIC ANEURYSM	I71.5, I71.6	THORACOABDOMINAL AORTIC ANEURYSM, RUPTURED/WITHOUT RUPTURE
745 – 747.99	CONGENITAL ANOMALIES	P29.3	PERSISTENT FETAL CIRCULATION
		Q20.0-Q28.9	CONGENITAL MALFORMATIONS OF THE CIRCULATORY SYSTEM
414 – 414.99	OTHER CHRONIC ISCHEMIC	I25.10-I25.9 (EXLUDING I25.2 OLD MI)	CHRONIC ISCHEMIC HEART DISEASE
410 – 410.99	ACUTE MYOCARDIAL INFARCT	I21.01-I22.9	STEMI AND NSTEMI MI
212.7	ALL OTHER HEART CONDITIONS	D15.1	BENIGN NEOPLASM OF HEART
398 – 398.99	ALL OTHER HEART CONDITIONS	I09.0	RHEUMATIC MYOCARDITIS

APPENDIX D CONTINUED

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
398 – 398.99 CONTINUED	ALL OTHER HEART CONDITIONS CONTINUED	I09.81-I09.9	OTHER/UNSPECIFIED RHEUMATIC HEART DISEASES
411 – 411.99	ALL OTHER HEART CONDITIONS	I20.0	UNSTABLE ANGINA
		I24.0-I24.9	OTHER ACUTE ISCHEMIC HEART DISEASE
		I25.110, I25.700, I25.710, I25.720, I25.730, I25.750, I25.760, I25.790	ATHEROSCLEROSIS WITH UNSTABLE ANGINA PECTORIS
423 – 423.9	ALL OTHER HEART CONDITIONS	I31.0-I31.9	OTHER DISEASES OF PERICARDIUM
425 – 425.9	ALL OTHER HEART CONDITIONS	A18.84	TUBERCULOSIS OF HEART
		I42.0-I43	CARDIOMYOPATHIES
427 – 427.9	ALL OTHER HEART CONDITIONS	I46.2-I46.9	CARDIAC ARREST
		I47.0-I47.9	PAROXYSMAL TACHYCARDIA
		I48.0-I48.92	ATRIAL FIBRILLATION AND FLUTTER
		I49.01-I49.9	OTHER CARDIAC ARRHYTHMIAS
		R00.1	BRADYCARDIA, UNSPECIFIED
428 – 428.9	ALL OTHER HEART CONDITIONS	I50.1-I50.9	HEART FAILURE
901 – 901.9	ALL OTHER HEART CONDITIONS	S25.00XA	UNSPECIFIED INJURY OF THORACIC AORTA, INITIAL ENCOUNTER
		S25.01XA	MINOR LACERATION OF THORACIC AORTA, INITIAL ENCOUNTER
		S25.02XA	MAJOR LACERATION OF THORACIC AORTA, INITIAL ENCOUNTER
		S25.09XA	OTHER SPECIFIED INJURY OF THORACIC AORTA, INITIAL ENCOUNTER
		S25.101A	UNSPECIFIED INJURY OF RIGHT INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER

APPENDIX D CONTINUED

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
901 – 901.9 CONTINUED	ALL OTHER HEART CONDITIONS CONTINUED	S25.102A	UNSPECIFIED INJURY OF LEFT INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.109A	UNSPECIFIED INJURY OF UNSPECIFIED INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.111A	MINOR LACERATION OF RIGHT INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.112A	MINOR LACERATION OF LEFT INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.119A	MINOR LACERATION OF UNSPECIFIED INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.121A	MAJOR LACERATION OF RIGHT INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.122A	MAJOR LACERATION OF LEFT INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.129A	MAJOR LACERATION OF UNSPECIFIED INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.191A	OTHER SPECIFIED INJURY OF RIGHT INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.192A	OTHER SPECIFIED INJURY OF LEFT INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.199A	OTHER SPECIFIED INJURY OF UNSPECIFIED INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.20XA	UNSPECIFIED INJURY OF SUPERIOR VENA CAVA, INITIAL ENCOUNTER
		S25.21XA	MINOR LACERATION OF SUPERIOR VENA CAVA, INITIAL ENCOUNTER

APPENDIX D CONTINUED

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
901 – 901.9 CONTINUED	ALL OTHER HEART CONDITIONS CONTINUED	S25.22XA	MAJOR LACERATION OF SUPERIOR VENA CAVA, INITIAL ENCOUNTER
		S25.29XA	OTHER SPECIFIED INJURY OF SUPERIOR VENA CAVA, INITIAL ENCOUNTER
		S25.301A	UNSPECIFIED INJURY OF RIGHT INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.302A	UNSPECIFIED INJURY OF LEFT INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.309A	UNSPECIFIED INJURY OF UNSPECIFIED INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.311A	MINOR LACERATION OF RIGHT INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.312A	MINOR LACERATION OF LEFT INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.319A	MINOR LACERATION OF UNSPECIFIED INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.321A	MAJOR LACERATION OF RIGHT INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.322A	MAJOR LACERATION OF LEFT INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.329A	MAJOR LACERATION OF UNSPECIFIED INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.391A	OTHER SPECIFIED INJURY OF RIGHT INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.392A	OTHER SPECIFIED INJURY OF LEFT INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER

APPENDIX D CONTINUED

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
901 – 901.9 CONTINUED	ALL OTHER HEART CONDITIONS CONTINUED	S25.399A	OTHER SPECIFIED INJURY OF UNSPECIFIED INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.401A	UNSPECIFIED INJURY OF RIGHT PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.402A	UNSPECIFIED INJURY OF LEFT PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.409A	UNSPECIFIED INJURY OF UNSPECIFIED PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.411A	MINOR LACERATION OF RIGHT PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.412A	MINOR LACERATION OF LEFT PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.419A	MINOR LACERATION OF UNSPECIFIED PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.421A	MAJOR LACERATION OF RIGHT PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.422A	MAJOR LACERATION OF LEFT PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.429A	MAJOR LACERATION OF UNSPECIFIED PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.491A	OTHER SPECIFIED INJURY OF RIGHT PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.492A	OTHER SPECIFIED INJURY OF LEFT PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.499A	OTHER SPECIFIED INJURY OF UNSPECIFIED PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.501A	UNSPECIFIED INJURY OF INTERCOSTAL BLOOD VESSELS, RIGHT SIDE, INITIAL ENCOUNTER

APPENDIX D CONTINUED

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
901 – 901.9 CONTINUED	ALL OTHER HEART CONDITIONS CONTINUED	S25.502A	UNSPECIFIED INJURY OF INTERCOSTAL BLOOD VESSELS, LEFT SIDE, INITIAL ENCOUNTER
		S25.509A	UNSPECIFIED INJURY OF INTERCOSTAL BLOOD VESSELS, UNSPECIFIED SIDE, INITIAL ENCOUNTER
		S25.511A	LACERATION OF INTERCOSTAL BLOOD VESSELS, RIGHT SIDE, INITIAL ENCOUNTER
		S25.512A	LACERATION OF INTERCOSTAL BLOOD VESSELS, LEFT SIDE, INITIAL ENCOUNTER
		S25.519A	LACERATION OF INTERCOSTAL BLOOD VESSELS, UNSPECIFIED SIDE, INITIAL ENCOUNTER
		S25.591A	OTHER SPECIFIED INJURY OF INTERCOSTAL BLOOD VESSELS, RIGHT SIDE, INITIAL ENCOUNTER
		S25.592A	OTHER SPECIFIED INJURY OF INTERCOSTAL BLOOD VESSELS, LEFT SIDE, INITIAL ENCOUNTER
		S25.599A	OTHER SPECIFIED INJURY OF INTERCOSTAL BLOOD VESSELS, UNSPECIFIED SIDE, INITIAL ENCOUNTER
		S25.801A	UNSPECIFIED INJURY OF OTHER BLOOD VESSELS OF THORAX, RIGHT SIDE, INITIAL ENCOUNTER
		S25.802A	UNSPECIFIED INJURY OF OTHER BLOOD VESSELS OF THORAX, LEFT SIDE, INITIAL ENCOUNTER
		S25.809A	UNSPECIFIED INJURY OF OTHER BLOOD VESSELS OF THORAX, UNSPECIFIED SIDE, INITIAL ENCOUNTER
		S25.811A	LACERATION OF OTHER BLOOD VESSELS OF THORAX, RIGHT SIDE, INITIAL ENCOUNTER
		S25.812A	LACERATION OF OTHER BLOOD VESSELS OF THORAX, LEFT SIDE, INITIAL ENCOUNTER
		S25.819A	LACERATION OF OTHER BLOOD VESSELS OF THORAX, UNSPECIFIED SIDE, INITIAL ENCOUNTER

APPENDIX D CONTINUED

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
901 – 901.9 CONTINUED	ALL OTHER HEART CONDITIONS CONTINUED	S25.891A	OTHER SPECIFIED INJURY OF OTHER BLOOD VESSELS OF THORAX, RIGHT SIDE, INITIAL ENCOUNTER
		S25.892A	OTHER SPECIFIED INJURY OF OTHER BLOOD VESSELS OF THORAX, LEFT SIDE, INITIAL ENCOUNTER
		S25.899A	OTHER SPECIFIED INJURY OF OTHER BLOOD VESSELS OF THORAX, UNSPECIFIED SIDE, INITIAL ENCOUNTER
		S25.90XA	UNSPECIFIED INJURY OF UNSPECIFIED BLOOD VESSEL OF THORAX, INITIAL ENCOUNTER
		S25.91XA	LACERATION OF UNSPECIFIED BLOOD VESSEL OF THORAX, INITIAL ENCOUNTER
		S25.99XA	OTHER SPECIFIED INJURY OF UNSPECIFIED BLOOD VESSEL OF THORAX, INITIAL ENCOUNTER
996.02, 996.03	ALL OTHER HEART CONDITIONS	T82.01XA	BREAKDOWN (MECHANICAL) OF HEART VALVE PROSTHESIS, INITIAL ENCOUNTER
		T82.02XA	DISPLACEMENT OF HEART VALVE PROSTHESIS, INITIAL ENCOUNTER
		T82.03XA	LEAKAGE OF HEART VALVE PROSTHESIS, INITIAL ENCOUNTER
		T82.09XA	OTHER MECHANICAL COMPLICATION OF HEART VALVE PROSTHESIS, INITIAL ENCOUNTER
		T82.211A	BREAKDOWN (MECHANICAL) OF CORONARY ARTERY BYPASS GRAFT, INITIAL ENCOUNTER
		T82.212A	DISPLACEMENT OF CORONARY ARTERY BYPASS GRAFT, INITIAL ENCOUNTER
		T82.213A	LEAKAGE OF CORONARY ARTERY BYPASS GRAFT, INITIAL ENCOUNTER
		T82.218A	OTHER MECHANICAL COMPLICATION OF CORONARY ARTERY BYPASS GRAFT, INITIAL ENCOUNTER

APPENDIX D CONTINUED

"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.

APPENDIX E

ICD-9-CM TO ICD-10-CM CODE TRANSLATION FOR APPENDIX B

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
745.0 – 747.99	CONGENITAL ANOMALIES	P29.3	PERSISTENT FETAL CIRCULATION
		Q20.0-Q28.9	CONGENITAL MALFORMATIONS OF THE CIRCULATORY SYSTEM
164.1	ALL OTHER HEART CONDITIONS	C38.0	MALIGNANT NEOPLASM OF HEART
		C45.2	MESOTHELIOMA OF PERICARDIUM
212.7	ALL OTHER HEART CONDITIONS	D15.1	BENIGN NEOPLASM OF HEART
390 - 429.99	ALL OTHER HEART CONDITIONS	A01.02	TYPHOID FEVER WITH HEART INVOLVEMENT
		A18.84	TUBERCULOSIS OF HEART
		I00-I09.9	RHEUMATIC FEVER/HEART DISEASES
		I10-I15.9	HYPERTENSIVE DISEASES
		I20.0-I25.9	ISCHEMIC HEART DISEASES
		I26.01-I28.9	PULMONARY HEART DISEASE/PULMONARY CIRCULATION DISEASES
		I30.0-I52	OTHER FORMS OF HEART DISEASE
		I97.0-197.191	INTRAOPERATIVE/POSTPROCEDURAL CARDIAC COMPLICATIONS
		N26.2	PAGE KIDNEY
		R00.1	BRADYCARDIA, UNSPECIFIED
		T80.0XXA	AIR EMBOLISM FOLLOWING INFUSION, TRANSFUSION AND THERAPEUTIC INJECTION, INITIAL ENCOUNTER
		T81.718A	COMPLICATION OF OTHER ARTERY FOLLOWING A PROCEDURE, NOT ELSEWHERE CLASSIFIED, INITIAL ENCOUNTER
		T81.72XA	COMPLICATION OF VEIN FOLLOWING A PROCEDURE, NOT ELSEWHERE CLASSIFIED, INITIAL ENCOUNTER

APPENDIX E CONTINUED

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
390 - 429.99 CONTINUED	ALL OTHER HEART CONDITIONS CONTINUED	T82.817A	EMBOLISM OF CARDIAC PROSTHETIC DEVICES, IMPLANTS AND GRAFTS, INITIAL ENCOUNTER
		T82.818A	EMBOLISM OF VASCULAR PROSTHETIC DEVICES, IMPLANTS AND GRAFTS, INITIAL ENCOUNTER
441.01	ALL OTHER HEART CONDITIONS	I71.01	DISSECTION OF THORACIC AORTA
441.03	ALL OTHER HEART CONDITIONS	I71.03	DISSECTION OF THORACOABDOMINAL AORTA
441.1	ALL OTHER HEART CONDITIONS	I71.1	THORACIC AORTIC ANEURYSM, RUPTURED
441.2	ALL OTHER HEART CONDITIONS	I71.2	THORACIC AORTIC ANEURYSM, WITHOUT RUPTURE
441.6	ALL OTHER HEART CONDITIONS	I71.5	THORACOABDOMINAL AORTIC ANEURYSM, RUPTURED
441.7	ALL OTHER HEART CONDITIONS	I71.6	THORACOABDOMINAL AORTIC ANEURYSM, WITHOUT RUPTURE
785.51	ALL OTHER HEART CONDITIONS	R57.0	CARDIOGENIC SHOCK
786.5-786.59	ALL OTHER HEART CONDITIONS	R07.1-R07.9	CHEST PAIN
901.0 – 901.9	ALL OTHER HEART CONDITIONS	S25.00XA	UNSPECIFIED INJURY OF THORACIC AORTA, INITIAL ENCOUNTER
		S25.01XA	MINOR LACERATION OF THORACIC AORTA, INITIAL ENCOUNTER
		S25.02XA	MAJOR LACERATION OF THORACIC AORTA, INITIAL ENCOUNTER
		S25.09XA	OTHER SPECIFIED INJURY OF THORACIC AORTA, INITIAL ENCOUNTER
		S25.101A	UNSPECIFIED INJURY OF RIGHT INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.102A	UNSPECIFIED INJURY OF LEFT INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER

APPENDIX E CONTINUED

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
901.0 – 901.9 CONTINUED	ALL OTHER HEART CONDITIONS CONTINUED	S25.109A	UNSPECIFIED INJURY OF UNSPECIFIED INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.111A	MINOR LACERATION OF RIGHT INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.112A	MINOR LACERATION OF LEFT INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.119A	MINOR LACERATION OF UNSPECIFIED INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.121A	MAJOR LACERATION OF RIGHT INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.122A	MAJOR LACERATION OF LEFT INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.129A	MAJOR LACERATION OF UNSPECIFIED INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.191A	OTHER SPECIFIED INJURY OF RIGHT INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.192A	OTHER SPECIFIED INJURY OF LEFT INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.199A	OTHER SPECIFIED INJURY OF UNSPECIFIED INNOMINATE OR SUBCLAVIAN ARTERY, INITIAL ENCOUNTER
		S25.20XA	UNSPECIFIED INJURY OF SUPERIOR VENA CAVA, INITIAL ENCOUNTER
		S25.21XA	MINOR LACERATION OF SUPERIOR VENA CAVA, INITIAL ENCOUNTER
		S25.22XA	MAJOR LACERATION OF SUPERIOR VENA CAVA, INITIAL ENCOUNTER

APPENDIX E CONTINUED

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
901.0 – 901.9 CONTINUED	ALL OTHER HEART CONDITIONS CONTINUED	S25.29XA	OTHER SPECIFIED INJURY OF SUPERIOR VENA CAVA, INITIAL ENCOUNTER
		S25.301A	UNSPECIFIED INJURY OF RIGHT INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.302A	UNSPECIFIED INJURY OF LEFT INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.309A	UNSPECIFIED INJURY OF UNSPECIFIED INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.311A	MINOR LACERATION OF RIGHT INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.312A	MINOR LACERATION OF LEFT INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.319A	MINOR LACERATION OF UNSPECIFIED INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.321A	MAJOR LACERATION OF RIGHT INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.322A	MAJOR LACERATION OF LEFT INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.329A	MAJOR LACERATION OF UNSPECIFIED INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.391A	OTHER SPECIFIED INJURY OF RIGHT INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.392A	OTHER SPECIFIED INJURY OF LEFT INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER
		S25.399A	OTHER SPECIFIED INJURY OF UNSPECIFIED INNOMINATE OR SUBCLAVIAN VEIN, INITIAL ENCOUNTER

APPENDIX E CONTINUED

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
901.0 – 901.9 CONTINUED	ALL OTHER HEART CONDITIONS CONTINUED	S25.401A	UNSPECIFIED INJURY OF RIGHT PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.402A	UNSPECIFIED INJURY OF LEFT PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.409A	UNSPECIFIED INJURY OF UNSPECIFIED PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.411A	MINOR LACERATION OF RIGHT PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.412A	MINOR LACERATION OF LEFT PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.419A	MINOR LACERATION OF UNSPECIFIED PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.421A	MAJOR LACERATION OF RIGHT PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.422A	MAJOR LACERATION OF LEFT PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.429A	MAJOR LACERATION OF UNSPECIFIED PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.491A	OTHER SPECIFIED INJURY OF RIGHT PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.492A	OTHER SPECIFIED INJURY OF LEFT PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.499A	OTHER SPECIFIED INJURY OF UNSPECIFIED PULMONARY BLOOD VESSELS, INITIAL ENCOUNTER
		S25.501A	UNSPECIFIED INJURY OF INTERCOSTAL BLOOD VESSELS, RIGHT SIDE, INITIAL ENCOUNTER

APPENDIX E CONTINUED

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
901.0 – 901.9 CONTINUED	ALL OTHER HEART CONDITIONS CONTINUED	S25.502A	UNSPECIFIED INJURY OF INTERCOSTAL BLOOD VESSELS, LEFT SIDE, INITIAL ENCOUNTER
		S25.509A	UNSPECIFIED INJURY OF INTERCOSTAL BLOOD VESSELS, UNSPECIFIED SIDE, INITIAL ENCOUNTER
		S25.511A	LACERATION OF INTERCOSTAL BLOOD VESSELS, RIGHT SIDE, INITIAL ENCOUNTER
		S25.512A	LACERATION OF INTERCOSTAL BLOOD VESSELS, LEFT SIDE, INITIAL ENCOUNTER
		S25.519A	LACERATION OF INTERCOSTAL BLOOD VESSELS, UNSPECIFIED SIDE, INITIAL ENCOUNTER
		S25.591A	OTHER SPECIFIED INJURY OF INTERCOSTAL BLOOD VESSELS, RIGHT SIDE, INITIAL ENCOUNTER
		S25.592A	OTHER SPECIFIED INJURY OF INTERCOSTAL BLOOD VESSELS, LEFT SIDE, INITIAL ENCOUNTER
		S25.599A	OTHER SPECIFIED INJURY OF INTERCOSTAL BLOOD VESSELS, UNSPECIFIED SIDE, INITIAL ENCOUNTER
		S25.801A	UNSPECIFIED INJURY OF OTHER BLOOD VESSELS OF THORAX, RIGHT SIDE, INITIAL ENCOUNTER
		S25.802A	UNSPECIFIED INJURY OF OTHER BLOOD VESSELS OF THORAX, LEFT SIDE, INITIAL ENCOUNTER
		S25.809A	UNSPECIFIED INJURY OF OTHER BLOOD VESSELS OF THORAX, UNSPECIFIED SIDE, INITIAL ENCOUNTER
		S25.811A	LACERATION OF OTHER BLOOD VESSELS OF THORAX, RIGHT SIDE, INITIAL ENCOUNTER
		S25.812A	LACERATION OF OTHER BLOOD VESSELS OF THORAX, LEFT SIDE, INITIAL ENCOUNTER

APPENDIX E CONTINUED

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
901.0 – 901.9 CONTINUED	ALL OTHER HEART CONDITIONS CONTINUED	S25.819A	LACERATION OF OTHER BLOOD VESSELS OF THORAX, UNSPECIFIED SIDE, INITIAL ENCOUNTER
		S25.891A	OTHER SPECIFIED INJURY OF OTHER BLOOD VESSELS OF THORAX, RIGHT SIDE, INITIAL ENCOUNTER
		S25.892A	OTHER SPECIFIED INJURY OF OTHER BLOOD VESSELS OF THORAX, LEFT SIDE, INITIAL ENCOUNTER
		S25.899A	OTHER SPECIFIED INJURY OF OTHER BLOOD VESSELS OF THORAX, UNSPECIFIED SIDE, INITIAL ENCOUNTER
		S25.90XA	UNSPECIFIED INJURY OF UNSPECIFIED BLOOD VESSEL OF THORAX, INITIAL ENCOUNTER
		S25.91XA	LACERATION OF UNSPECIFIED BLOOD VESSEL OF THORAX, INITIAL ENCOUNTER
		S25.99XA	OTHER SPECIFIED INJURY OF UNSPECIFIED BLOOD VESSEL OF THORAX, INITIAL ENCOUNTER
996.02	ALL OTHER HEART CONDITIONS	T82.01XA	BREAKDOWN (MECHANICAL) OF HEART VALVE PROSTHESIS, INITIAL ENCOUNTER
		T82.02XA	DISPLACEMENT OF HEART VALVE PROSTHESIS, INITIAL ENCOUNTER
		T82.03XA	LEAKAGE OF HEART VALVE PROSTHESIS, INITIAL ENCOUNTER
		T82.09XA	OTHER MECHANICAL COMPLICATION OF HEART VALVE PROSTHESIS, INITIAL ENCOUNTER

"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.

APPENDIX E CONTINUED

"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.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR POSITRON EMISSION TOMOGRAPHY (PET) 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, replacement, expansion, or acquisition of PET scanner services, and the delivery of these services under Part 222 of the Code. Pursuant to Part 222 of the Code PET scanner services are 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) "Central service coordinator" means the legal entity that has operational responsibility for a mobile PET scanner service.

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

(d) "Existing PET scanner" means an operational PET scanner used to provide PET services on the date an application is submitted to the Department.

(e) "Existing PET scanner service" means an operational PET scanner service providing PET scanner services at one site in the case of a fixed PET service or at each host site in the case of a mobile PET service on the date an application is submitted to the Department.

(f) "Health service area" or "HSA" means the groups of counties listed in Appendix A.

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

(h) "Host site" means the geographic address at which a mobile PET scanner is authorized by CON to provide mobile PET scanner services.

(i) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C.1396 to 1396g and 1396i to 1396u.

(j) "Michigan Inpatient Data Base" or "MIDB" means the data base compiled by the Michigan Health and Hospital Association or successor organization. The data base consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.

(k) "Mobile PET scanner" means a PET scanner unit and transporting equipment operated by a central service coordinator that serves two or more host sites.

(l) "Mobile PET scanner network" means the route (i.e., all host sites) that the central service coordinator is authorized to serve under CON.

(m) "Patient visit" means a single session utilizing a PET scanner during which 1 or more PET procedures are performed.

(n) "Pediatric patient" means any patient less than 18 years of age.

(o) "PET procedure" means the acquisition of a single image or image sequence involving a single injection of tracer.

(p) "PET scan" means one (1) or more PET procedures performed during a single patient visit.

(q) "PET scanner" means an FDA-approved full or partial ring scanner or coincidence system that has a crystal at least 5/8-inch thick, techniques to minimize or correct for scatter and/or randoms, and digital detectors and iterative reconstruction. Further, the term does include PET/computed tomography

(CT) and FDA-approved PET/magnetic resonance imagining (MRI) scanner hybrids. If the PET/CT scanner hybrid will be used for CT scans only in conjunction with the PET scan, then no separate CON is required for that CT use. If the FDA-approved PET/MRI scanner hybrid will be used for MRI scans only in conjunction with the PET scan, then no separate CON is required for that MRI use. The term does not include single-photon emission computed tomography systems (SPECT), x-ray CT systems, magnetic resonance, ultrasound computed tomographic systems, gamma cameras modified for either non-coincidence or coincidence imaging, or similar technology.

(r) "PET scanner services" or "PET services" means either the utilization of a PET unit(s) at one site in the case of a fixed PET service or at each host site in the case of a mobile PET service.

(s) "SPECT" means single photon emission computed tomography.

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

Section 3. Requirements to initiate a PET scanner service

Sec. 3. An applicant proposing to initiate PET scanner services shall demonstrate the following, as applicable to the proposed project.

(1) The applicant shall demonstrate the proposed site provides the following services and specialties:

(a) nuclear medicine services as documented by a certificate from the US Nuclear Regulatory Commission,

(b) single photon emission computed tomography (SPECT) services,

(c) computed tomography (CT) scanning services,

(d) magnetic resonance imaging (MRI) services,

(e) cardiac catheterization services,

(f) open heart surgery,

(g) thoracic surgery,

(h) cardiology,

(i) oncology,

(j) radiation oncology,

(k) neurology,

(l) neurosurgery, and

(m) psychiatry.

(2) If the proposed site does not provide any of the services listed in subsection (1) on-site, the applicant shall provide written contracts or agreements with a hospital(s) located within the same planning area or 25-mile radius of the proposed site for the services not provided.

(3) The applicant shall demonstrate the proposed site has an on-site source of radiopharmaceuticals. If the proposed site does not provide an on-site source of radiopharmaceuticals, the applicant shall provide a written contract or agreement that demonstrates a reliable supply of radiopharmaceuticals.

(4) An applicant proposing to initiate a fixed PET scanner service with its first PET scanner shall project 2,600 PET data units or shall demonstrate all of the following:

(a) The applicant is currently a host site being served by one or more mobile PET scanner services.

(b) The applicant has performed:

(i) 1,700 PET equivalents in the most recent 12-month period verifiable by the Department for a host site in a metropolitan statistical area county, or

(ii) 1,500 PET equivalents in the most recent 12-month period verifiable by the Department for a host site in a rural or micropolitan statistical area county.

(c) The applicant shall install the fixed PET unit at the same site as the existing host site or within a 10-mile radius of the existing host site for a metropolitan statistical area county or a 25-mile radius for a rural or micropolitan statistical area.

(d) The applicant agrees to cease operation as a host site and not become a host site for at least 12 months from the date the fixed PET scanner becomes operational. This requirement shall not apply if the applicant is installing an FDA-approved PET/MRI scanner hybrid.

(5) An applicant proposing to initiate a mobile PET scanner service with its first mobile PET scanner shall project 2,100 PET data units.

(a) Of the 2,100 PET data units, the applicant shall project a minimum of 360 PET data units within a 20-mile radius of each proposed host site for planning area 1, or 240 PET data units per host site for any other planning area, for the proposed service.

(b) The application for the mobile PET scanner service is accompanied by at least two host site applications.

(c) Each applicant provides a route schedule for the proposed mobile PET scanner service.

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

(6) An applicant proposing to initiate a host site on a proposed or existing mobile PET 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.

(c) The applicant has not initiated fixed PET scanner services under subsection 3(4) within the most recent 12-month period as of the date the application is submitted to the Department.

(d) An applicant initiating a host site in HSA 8 on a mobile PET scanner service that operates predominantly outside of Michigan shall demonstrate 240 PET data units from planning area 6.

(7) An applicant proposing to initiate PET scanner services as an existing host site on a different mobile PET 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.

(c) 50 PET equivalents were performed in the most recent 12-month period verifiable by the Department from an existing mobile PET scanner service at the existing host site.

Section 4. Requirements to replace an existing PET scanner(s) or PET scanner service

Sec. 4. Replacing a PET scanner(s) means a change in the scanner equipment or relocation of the service to a new site. An upgrade to software or components of an existing scanner does not constitute replacement of a PET scanner. An applicant proposing to replace an existing PET scanner(s) or PET scanner service shall demonstrate the following, as applicable to the proposed project.

(1) An applicant proposing to replace a PET scanner(s) shall demonstrate each of the following:

(a) The replacement scanner(s) is the same type (fixed or mobile) as the scanner(s) to be replaced.

(b) The scanner(s) to be replaced is fully depreciated according to generally accepted accounting principles or either of the following:

(i) The existing scanner(s) poses a threat to the safety of the patients.

(ii) The replacement scanner(s) offers technological improvements that enhance quality of care, increase efficiency, and reduce operating costs and patient charges.

(c) The applicant agrees that the PET scanner(s) to be replaced will be removed from service on or before beginning operation of the replacement scanner(s).

(2) An applicant proposing to replace a fixed PET scanner service to a new site shall demonstrate the following:

(a) The proposed site is within a 10-mile radius of the existing site for a metropolitan statistical area county or a 25-mile radius for a rural or micropolitan statistical area county.

(b) The existing fixed PET scanner(s) performed 500 PET equivalents per fixed scanner in the most recent 12-month period verifiable by the Department.

(c) The existing fixed PET scanner service has been in operation for at least 36 months as of the date of the application submitted to the Department.

Section 5. Requirements to expand a PET scanner service

Sec. 5. An applicant proposing to expand a PET scanner service shall demonstrate the following, as applicable to the proposed project. This section does not apply to dedicated research, dedicated pediatric, or positron emission mammography (PEM) scanners.

(1) An applicant proposing to add a fixed PET scanner(s) to an existing fixed PET scanner service shall demonstrate the following:

(a) 1,900 PET equivalents were performed per existing and approved fixed PET scanner(s) in the most recent 12-month period verifiable by the Department for an applicant in a metropolitan statistical area county, or

(b) 1,700 PET equivalents were performed per existing and approved fixed PET scanner(s) in the most recent 12-month period verifiable by the Department for an applicant in a rural or micropolitan statistical area county.

(c) The additional PET scanner(s) shall be located at the same site.

(2) An applicant proposing to add a mobile PET scanner(s) to an existing mobile PET scanner service shall demonstrate the following:

(a) 2,000 PET equivalents were performed per existing and approved mobile scanner(s) in the most recent 12-month period verifiable by the Department for an applicant serving at least one existing host site in a metropolitan statistical area county, or

(b) 1,800 PET equivalents were performed per existing and approved scanner(s) in the most recent 12-month period verifiable by the Department for an applicant serving only host sites in rural or micropolitan statistical area counties.

(3) An applicant proposing to add a fixed PET scanner to an existing fixed PET scanner service that also receives mobile PET scanner services shall demonstrate the following:

(a) The applicant is currently a host site being served by one or more mobile PET scanner services.

(b) The applicant has performed:

(i) An average of 1,900 pet equivalents for the host site and each of the existing and approved fixed scanners in the most recent 12-month period verifiable by the Department for a host site in a metropolitan statistical area county, or

(ii) An average of 1,700 PET equivalents for the host site and each of the existing and approved fixed scanners in the most recent 12-month period verifiable by the Department for a host site in a rural or micropolitan statistical area county.

(c) The applicant agrees to cease operation as a host site and not become a host site for at least 12 months from the date the fixed scanner becomes operational.

Section 6. Requirements to acquire a PET scanner service or scanner(s)

Sec. 6. Acquiring a PET scanner service and its scanner(s) means obtaining possession and control by contract, ownership, lease, or other comparable arrangement and renewal of lease for an existing fixed or mobile PET scanner. An applicant proposing to acquire a PET scanner service shall demonstrate the following, as applicable to the proposed project.

(1) For the first application proposing to acquire an existing fixed, mobile, or host site PET scanner service, other than a renewal of lease, on or after November 21, 2011, the existing PET service and its scanner(s) shall not be required to be in compliance with the applicable volume requirements set forth in this section.

(2) An applicant proposing to acquire an existing fixed or mobile PET scanner service shall demonstrate that the existing fixed or mobile scanner(s) performed an average of 500 PET equivalents per scanner in the most recent 12-month period verifiable by the Department.

(3) An applicant proposing to acquire an existing host site shall demonstrate that the existing host site has performed 50 PET equivalents in the most recent 12-month period verifiable by the Department.

(4) An applicant proposing to renew a lease for an existing fixed or mobile PET scanner(s) shall demonstrate that the renewal of the lease is more cost effective than replacing the scanner(s).

Section 7. Requirements for a dedicated research fixed PET scanner

Sec. 7. An applicant proposing to add a fixed PET scanner to an existing PET scanner service for exclusive research use shall demonstrate the following:

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

(2) The dedicated research PET 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 applicant has access to a cyclotron for accelerating charged particles to high energies by means of electromagnetic fields.

(4) The proposed site can have no more than three dedicated research fixed PET scanners approved under this Section.

Section 8. Requirements for a dedicated pediatric PET scanner

Sec. 8. An applicant proposing to initiate a PET scanner service, or add a fixed PET scanner to expand an existing PET scanner service, for dedicated pediatric PET use shall demonstrate the following:

(1) The applicant agrees that the dedicated pediatric PET scanner will be used primarily (70% or more of the scans) for patients under 18 years of age.

(2) The applicant shall demonstrate the existing site provided the following for the most recent calendar year or a continuous 12-month period at the time the application is submitted to the Department:
(a) at least 7,000 pediatric (< 18 years old) discharges, excluding normal newborns,
(b) at least 5,000 pediatric (< 18 years old) surgeries, and
(c) at least 50 new pediatric cancer cases on its cancer registry.

(3) The applicant shall have an active medical staff at the time the application is submitted to the Department that includes physicians who are fellowship-trained in the following pediatric specialties:
(a) radiology (at least two staff members)
(b) anesthesiology
(c) cardiology
(d) critical care
(e) gastroenterology
(f) hematology/oncology

(g) neurology
(h) neurosurgery
(i) orthopedic surgery
(j) pathology
(k) pulmonology
(l) surgery
(m) neonatology

(4) The applicant shall have in operation the following pediatric specialty programs at the time the application is submitted to the Department:
(a) bone marrow transplant program
(b) sedation program
(c) open heart program

(5) The applicant meets the requirements of Section 3(1) through 3(4) if the applicant is initiating a PET scanner service with a dedicated pediatric fixed PET scanner.

(6) The proposed site can have no more than two dedicated pediatric fixed PET scanners approved under this section.

Section 9. Requirements for a positron emission mammography (PEM) scanner

Sec. 9. An applicant proposing to add a PEM scanner service to an existing PET scanner service shall demonstrate the following, as applicable to the proposed project.

(1) An applicant proposing to add a fixed PEM scanner to an existing fixed PET scanner site shall demonstrate the following:
(a) The applicant is certified through the American College of Radiology (ACR) as a Breast Imaging Center of Excellence (BICOE) at the time the application is submitted to the Department.
(b) The applicant has a fixed PET scanner service and has performed 1,000 PET equivalents per scanner at the site in the most recent 12-month period verifiable by the Department, or the applicant operates a comprehensive cancer center recognized by the National Cancer Institute and contracts with a facility that has a fixed PET scanner service.
(c) The proposed site can have no more than one fixed PEM scanner approved under this section.

(2) An applicant proposing to add a mobile PEM scanner to an existing mobile PET scanner service shall demonstrate the following:
(a) The central service coordinator application for a mobile PEM scanner shall be accompanied by at least five (5) companion host site applications for initiation of mobile PEM scanner services. The proposed host sites have not received mobile PEM scanner services within the most recent 12-month period.
(b) The applicant has performed an average of 500 PET equivalents per scanner on the existing mobile PET network in the most recent 12-month period verifiable by the Department.
(c) The applicant provides a route schedule for the proposed mobile PEM scanner service.
(d) The applicant provides a draft contract for PEM services between the proposed host sites and central service coordinator.
(e) The proposed network can have no more than one mobile PEM scanner approved under this section.

(3) An applicant, whether an existing fixed PET scanner site or host site, proposing to initiate mobile PEM scanner services as a host site shall demonstrate the following:
(a) The applicant is certified through the ACR as a BICOE site at the time the application is submitted to the Department.

(b) The applicant has a fixed PET scanner site or host site and has performed 100 PET equivalents in the most recent 12-month period verifiable by the Department, or the applicant operates a comprehensive cancer center recognized by the National Cancer Institute and contracts with a facility that has a fixed or mobile PET scanner service.
(c) The applicant provides a proposed route schedule for the mobile PEM scanner service.
(d) The applicant provides a draft contract for PEM services between the host site and central service coordinator.

(4) An applicant proposing to add an existing PEM scanner host site to an existing mobile PEM scanner service shall demonstrate the following:
(a) The host site has performed mobile PEM scanner service within the most recent 12-month period as of the date an application is submitted to the Department.
(b) The proposed site is certified through the ACR as a BICOE site at the time the application is submitted to the Department.
(c) The applicant provides a proposed route schedule for the mobile PEM scanner service.
(d) The applicant provides a draft contract for PEM services between the host site and central service coordinator.

Section 10. Requirement for Medicaid participation

Sec. 10. 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 (6) months from the offering of services if a CON is approved.

Section 11. Project delivery Requirements and terms of approval for all applicants

Sec. 11. An applicant shall agree that, if approved, the PET scanner services shall be delivered in compliance with the following terms of approval.

(1) Compliance with these standards.

(2) Compliance with the following quality assurance requirements:
(a) A PET scanner service shall be staffed so that screening of requests for and interpretation of PET procedures will be carried out by a physician(s) with appropriate training and familiarity with the appropriate diagnostic use and interpretation of cross-sectional images of the anatomical region(s) to be examined. For purposes of evaluating this subsection, the Department shall consider it prima facie evidence as to the training of the physician(s) if the physician is board certified or board qualified in nuclear medicine or nuclear radiology. However, an applicant may submit, and the Department may accept, other evidence that the physician(s) is qualified to operate the PET service/scanner. The physician(s) must be on-site or available through telecommunication capabilities to participate in the screening of patients for PET procedures and to provide other consultation services.
(b) The PET scanner service shall include the following personnel, employed directly or on a contractual basis: a technologist with training in PET scanning and a physicist. The physicist must be board certified or eligible for certification by the American Board of Radiology or an equivalent organization.
(c) The PET scanner service shall have a physician on-site or immediately available to the PET scanner service at all times when patients are undergoing PET procedures.
(d) The applicant maintains the services and specialties as set forth in Section 3(1) through 3(4).

(3) Compliance with the following access to care requirements:
(a) The PET scanner service shall accept referrals for PET scanner services from all appropriately licensed practitioners.
(b) The PET scanner 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 PET scanner service shall not deny PET scanner services to any individual based on ability to pay or source of payment.

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

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

(a) The PET scanners shall be operating at an average of 500 PET equivalents per scanner during the second 12 months of operations, and annually thereafter. This requirement shall be waived during review of applications under sections 4(1) and 6(4), if applicable. In meeting these requirements, an applicant shall not include any PET scans performed on a PET scanner used exclusively for research approved pursuant to Section 7, for a dedicated pediatric PET scanner approved pursuant to Section 8, or for a PEM scanner approved pursuant to Section 9.

(b) The PET scanner service shall participate in a data collection system established and administered by the Department or its designee. The data may include, but are not limited to, clinical scan data, annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, and the volume of care provided to patients from all payor sources. The applicant shall provide the required data on a separate basis for each separate and distinct site, PET scanner, or PET scanner service as required by the Department, in a format established by the Department. The Department may elect to verify the data through on-site review of appropriate records.

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

(5) Compliance with the following dedicated research PET scanner requirements, if applicable:

(a) The capital and operating costs relating to the dedicated research PET scanner shall be charged only to a specific research account(s) and not to any patient or third- party payor.

(b) The dedicated research pet scanner shall not be used for any purposes other than as approved by the Institutional Review Board.

(c) The dedicated research PET scanner will be used primarily (70% or more of the scans) for research purposes only.

(6) Compliance with the following dedicated pediatric PET scanner requirements, if applicable:

(a) The dedicated pediatric PET scanner will be used primarily (70% or more of the scans) for patients under 18 years of age.

(b) Shall maintain active medical staff in the applicable pediatric specialties and pediatric specialty programs as set forth in the section.

(7) Compliance with the following PEM scanner requirements, if applicable:

(a) The PEM scanner service must maintain ACR accreditation as a BICOE site verifiable by the Department.

(8) Compliance with the following mobile PET scanner requirements, if applicable:

(a) The central service coordinator for a mobile PET scanner service shall notify the Department 30 days prior to dropping an existing host site.

(b) Each host site must have at least one physician who is board certified or board eligible in nuclear medicine or nuclear radiology on its medical staff. The physician(s) shall be responsible for establishing patient examination and infusion protocol, and providing for the interpretation of scans performed.

(c) Each host site shall provide a properly prepared parking pad for the mobile PET scanner unit, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as an enclosed canopy or an enclosed corridor).

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

(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 12. Methodology for computing the projected PET data units

Sec. 12. An applicant being reviewed under Section 3 shall apply the methodology set forth in this section in computing the projected number of PET data units.

(1) Identify the number of diagnosis-specific new cancer cases documented in accordance with the requirements of Section 13.

(a) Combine the number of cancer cases for lung (site codes C340-C349), esophagus (site codes C150-C159), colorectal (site codes C180-C209), lymphoma (morphology codes (9590-9729), melanoma (morphology codes 8720-8790), and head & neck [site codes C000-C148, C300-C329, C410, C411, C470 or C490 excluding C440-C444 (skin of head and neck), and additional codes approved by national coverage determination]. Use the name "combined" for this grouping.

(b) Multiply the number resulting from the calculation in "combined" cancer cases identified in subsection (1)(a) by 0.8, which is the estimated probability that a "combined" cancer case will require a PET scan.

(c) Multiply the number resulting from the calculation in subsection (1)(b) by 2.5, which is the estimated number of PET scans needed for each patient requiring a PET scan.

(2) Identify the number of diagnosis-specific new cancer cases documented in accord with the requirements of section 13.

(a) Multiply the number of breast cancer cases (site codes C500-C509) by 0.25, which is the estimated probability that a breast cancer case will require a PET scan.

(b) Multiply the number resulting from the calculation in subsection (2)(a) by 1.0, which is the estimated number of PET scans needed for each patient requiring a PET scan.

(3) Multiply the number of diagnostic cardiac catheterization cases identified in accord with the requirements of Section 15 by 0.1, which is the estimated probability that a patient having a diagnostic cardiac catheterization will require a PET scan.

(4) Multiply the number of intractable epilepsy cases (ICD-9-CM codes 345.01, 345.11, 345.41, 345.51, 345.61, 345.71, 345.81, or 345.91, SEE APPENDIX D FOR ICD-10-CM CODES) identified in accord with the requirements of Section 16 by 1.0, which is the estimated probability that a patient having an intractable epilepsy procedure will require a PET scan. Multiply the number resulting from the calculation in subsection (3) by 1.0, which is the estimated number of PET scans needed for each patient requiring a PET scan.

(5) Sum the numbers resulting from the calculations in subsections (1) through (4) to determine the total number of projected PET data units.

(6) Multiply the result calculated in subsection (5) above by a factor of 3.0 if the applicant is proposing to serve only planning area 6 to determine the total number of projected PET data units.

(7) Multiply the result calculated in subsection (5) above by a factor of 2.0 if the applicant is proposing to serve only planning area 5 to determine the total number of projected PET data units.

Section 13. Commitment of diagnosis-specific new cancer cases

Sec. 13. An applicant proposing to use diagnosis-specific new cancer cases shall demonstrate all of the following:

(1) Only those cancer diagnoses identified in Section 12(1) and 12(2) shall be included.

(2) Each entity contributing diagnosis-specific new cancer case data provides, as part of the application at the time it is submitted to the Department, a signed governing body resolution that identifies the number of diagnosis-specific cancer cases being committed to the application and that states no current or future diagnosis-specific new cancer case data will be used in support of any other application for a PET unit for a period of five (5) years from the date of start of operations of the approved PET scanner service for which data are being committed. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

(a) For fixed PET scanner services, the geographic location of each entity contributing diagnosis-specific new cancer case data is in the same planning area as the proposed PET service.

(b) For mobile PET scanner services, the geographic location of each entity contributing diagnosis-specific new cancer case data in the planning area(s) for which the proposed PET service contains a proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical area counties or 25-mile radius for metropolitan statistical area counties.

(c) No entity contributing diagnosis-specific new cancer case data has previously committed or is committing data to another service that is less than five (5) years from the start of operations of that service.

(3) No entity currently operating or approved to operate a PET scanner service shall contribute diagnosis-specific new cancer cases.

(4) The Department may not consider a withdrawal of diagnosis-specific new cancer case data during the 120-day application review cycle following the date on which the Department review of the application commences or after a proposed decision to approve the application has been issued unless the application is denied, withdrawn, or expired. The withdrawal must be submitted to the Department in the form of a governing body resolution that contains the specific CON application number to which the data were originally committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in which the governing body authorized the withdrawal of the data, the governing body president's signature, and the date of the signature.

Section 14. Documentation of diagnosis-specific new cancer case data

Sec. 14. An applicant required to document volumes of diagnosis-specific new cancer cases shall submit, as part of its application at the time it is submitted to the Department, documentation from the Division for Vital Records and Health Statistics verifying the number of diagnosis-specific new cancer cases provided in support of the application for the most recent calendar year for which verifiable data are available from the state registrar. if the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department. Diagnosis-specific new cancer case data supporting an application under these standards shall be submitted to the Division for Vital Records and Health Statistics using a format and media specified in instructions from the Department of Community Health.

Section 15. Commitment and documentation of diagnostic cardiac catheterization data

Sec. 15. An applicant proposing to use diagnostic cardiac catheterization data shall demonstrate all of the following:

(1) Each entity contributing diagnostic cardiac catheterization data provides, as part of the application at the time it is submitted to the Department, a signed governing body resolution that identifies the number of diagnostic cardiac catheterization cases (sessions) committed to the application and that states no current or future diagnostic cardiac catheterization data will be used in support of any other

application for a PET unit for the duration of the PET service for which data are being committed for a period of five (5) years from the date of start of operations of the approved PET service for which data are being committed. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

(a) For fixed PET scanner services, the geographic location of each entity contributing diagnostic cardiac catheterization data is in the same planning area as the proposed PET unit/service.

(b) For mobile PET scanner services, the geographic location of each entity contributing diagnostic cardiac catheterization case data in the planning area(s) for which the proposed PET service contains a proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical area counties or 25-mile radius for metropolitan statistical area counties.

(c) No entity contributing diagnostic cardiac catheterization data has previously committed or is committing data to another service that is less than five (5) years from the start of operations of that service.

(d) The diagnostic cardiac catheterization case data is from the most recently completed report(s) of the annual survey produced by the Department, and the contributing entity has CON approval to provide diagnostic cardiac catheterization services.

(2) No entity currently operating or approved to operate a PET scanner service shall contribute diagnostic cardiac catheterization case data.

(3) The Department may not consider a withdrawal of diagnostic cardiac catheterization case data during the 120-day application review cycle following the date on which the Department review of the application commences or after a proposed decision to approve the application has been denied unless the application is denied, withdrawn, or expired. The withdrawal must be submitted to the Department in the form of a governing body resolution that contains the specific CON application number to which the data were originally committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in which the governing body authorized the withdrawal of the data, the governing body president's signature, and the date of the signature.

Section 16. Commitment and documentation of intractable epilepsy data

Sec. 16. An applicant proposing to use intractable epilepsy cases shall demonstrate all of the following:

(1) Each entity contributing intractable epilepsy data provides, as part of the application at the time it is submitted to the Department, a signed governing body resolution that identifies the number of intractable epilepsy cases committed to the application and that states no current or future intractable epilepsy case data will be used in support of any other application for a PET unit for the duration of the PET service for which the data are being committed for a period of five (5) years from the date of start of operations of the approved PET service for which data are being committed. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

(a) For fixed PET scanner services, the geographic location of each entity contributing intractable epilepsy case data is in the same planning area as the proposed PET unit/service.

(b) For mobile PET scanner services, the geographic location of each entity contributing intractable epilepsy case data in the planning area(s) for which the proposed PET scanner service contains a proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical area counties or 25-mile radius for metropolitan statistical area counties.

(c) No entity contributing intractable epilepsy case data has previously committed or is committing data to another service that is less than five (5) years from the start of operations of that service.

(d) The intractable epilepsy case data is from the most recent Michigan Inpatient Data Base (MIDB) available to the Department.

(2) No entity currently operating or approved to operate a scanner shall contribute intractable epilepsy case data.

(3) The Department may not consider a withdrawal of intractable epilepsy case data during the 120-day application review cycle following the date on which the Department review of the application commences or after a proposed decision to approve the application unless the application is denied, withdrawn, or expired. The withdrawal must be submitted to the Department in the form of a governing body resolution that contains the specific CON application number to which the data were originally committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in which the governing body authorized the withdrawal of the data, the governing body president's signature, and the date of the signature.

Section 17. Methodology for computing PET equivalents

Sec. 17. PET equivalents shall be calculated as follows:

TABLE 1
PET EQUIVALENTS

Scan Category	Weight
Simple [1]	0.75
Standard [2]	1.0
Complex [3]	1.5

[1] Brain and single cardiac scans.

[2] Mid-skull to mid-thigh scans.

[3] Inpatient, radiation treatment when patient position device is used, cardiac rest/stress perfusion and metabolism, standard study with additional limited scan, pediatric, and total body scans.

Section 18. Department inventory of PET scanners

Sec. 18. The Department shall maintain and publicly post on its web site a list of PET scanner services annually.

Section 19. Comparative reviews; effect on prior planning policies

Sec. 19. Proposed projects reviewed under these standards shall not be subject to comparative review. These CON review standards supersede and replace the CON standards for PET scanner services approved by the CON Commission on September 22, 2011 and effective November 21, 2011.

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

APPENDIX B

Counties by Health service areas assigned to each planning area are as follows:

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

APPENDIX C

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

65 F.R., p. 82238 (December 27, 2000)
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
345.01	INTRACTABLE EPILEPSY CASES	G40.311	GENERALIZED IDIOPATHIC EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.319	GENERALIZED IDIOPATHIC EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE, WITHOUT STATUS EPILEPTICUS
		G40.A11	ABSENCE EPILEPTIC SYNDROME, INTRACTABLE, WITH STATUS EPILEPTICUS
345.11	INTRACTABLE EPILEPSY CASES	G40.311	GENERALIZED IDIOPATHIC EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.319	GENERALIZED IDIOPATHIC EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE, WITHOUT STATUS EPILEPTICUS
345.41	INTRACTABLE EPILEPSY CASES	G40.211	LOCALIZATION-RELATED (FOCAL) (PARTIAL) SYMPTOMATIC EPILEPSY AND EPILEPTIC SYNDROMES WITH COMPLEX PARTIAL SEIZURES, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.219	LOCALIZATION-RELATED (FOCAL) (PARTIAL) SYMPTOMATIC EPILEPSY AND EPILEPTIC SYNDROMES WITH COMPLEX PARTIAL SEIZURES, INTRACTABLE, WITHOUT STATUS EPILEPTICUS
345.51	INTRACTABLE EPILEPSY CASES	G40.011	LOCALIZATION-RELATED (FOCAL) (PARTIAL) IDIOPATHIC EPILEPSY AND EPILEPTIC SYNDROMES WITH SEIZURES OF LOCALIZED ONSET, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.019	LOCALIZATION-RELATED (FOCAL) (PARTIAL) IDIOPATHIC EPILEPSY AND EPILEPTIC SYNDROMES WITH SEIZURES OF LOCALIZED ONSET, INTRACTABLE, WITHOUT STATUS EPILEPTICUS

765
766

APPENDIX D CONTINUED

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
345.51 CONTINUED	INTRACTABLE EPILEPSY CASES CONTINUED	G40.111	LOCALIZATION-RELATED (FOCAL) (PARTIAL) SYMPTOMATIC EPILEPSY AND EPILEPTIC SYNDROMES WITH SIMPLE PARTIAL SEIZURES, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.119	LOCALIZATION-RELATED (FOCAL) (PARTIAL) SYMPTOMATIC EPILEPSY AND EPILEPTIC SYNDROMES WITH SIMPLE PARTIAL SEIZURES, INTRACTABLE, WITHOUT STATUS EPILEPTICUS
345.61	INTRACTABLE EPILEPSY CASES	G40.411	OTHER GENERALIZED EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.419	OTHER GENERALIZED EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE, WITHOUT STATUS EPILEPTICUS
345.71	INTRACTABLE EPILEPSY CASES	G40.111	LOCALIZATION-RELATED (FOCAL) (PARTIAL) SYMPTOMATIC EPILEPSY AND EPILEPTIC SYNDROMES WITH SIMPLE PARTIAL SEIZURES, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.119	LOCALIZATION-RELATED (FOCAL) (PARTIAL) SYMPTOMATIC EPILEPSY AND EPILEPTIC SYNDROMES WITH SIMPLE PARTIAL SEIZURES, INTRACTABLE, WITHOUT STATUS EPILEPTICUS
345.81	INTRACTABLE EPILEPSY CASES	G40.803	OTHER EPILEPSY, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.804	OTHER EPILEPSY, INTRACTABLE, WITHOUT STATUS EPILEPTICUS
		G40.89	OTHER SEIZURES
345.91	INTRACTABLE EPILEPSY CASES	G40.411	OTHER GENERALIZED EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.419	OTHER GENERALIZED EPILEPSY AND EPILEPTIC SYNDROMES, INTRACTABLE, WITHOUT STATUS EPILEPTICUS

767

APPENDIX D CONTINUED

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
		G40.911	EPILEPSY, UNSPECIFIED, INTRACTABLE, WITH STATUS EPILEPTICUS
		G40.919	EPILEPSY, UNSPECIFIED, INTRACTABLE, WITHOUT STATUS EPILEPTICUS

"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.

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

MEMO

To: **CON Commission**
From: **Karen J. Messick, MPA, LNHA**
CON Workgroup Chair
Date: **March 18, 2014 CON Commission meeting**
RE: **CON Workgroup update**

The CON Workgroup has gathered three times: December 18, 2013, January 16, 2014, and February 13, 2014. Our next meeting is scheduled for Thursday, March 27, 2014.

The workgroup was tasked with five charges. Charge 1 was to consider modifications to the comparative review criteria. By group decision, we have spent the majority of our efforts on this charge. Currently, we have formed a sub-group to work on a recommendation with regard to Section 10(2) and 10(3) of the comparative review criteria that concerns Medicare and Medicaid certification. The sub-group has reported to me that they will make their recommendation at the March 27th workgroup meeting.

Another sub-group was formed and has presented their recommendation for Section 10(5) of the comparative review criteria regarding culture change.

The Department has been very helpful. Spreadsheets were created to show all the comparative review criteria, scoring, etc. Other supporting information has also been provided by the department to help us in our discussions. We are using the spreadsheets to work through Section 10 of the comparative review and will develop final recommendations accordingly.

Our intention for spending the amount of time we have on Charge 1 is to ensure we are making recommendations that not only make sense now but also in the future as health care reform begins to make its mark on skilled beds.

We have been keeping Charges 2 and 3 in front of us as we work on comparative review criteria. We intend to move fairly quickly through Charges 2 and 3 once we have completed the work on Charge 1.

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. I have attached a copy of the letter for the CON Commission with this report update. The workgroup agreed unanimously with the recommendation to remove Charge 4.

We are hoping to complete our work at the March 27th meeting; however, we have scheduled two additional dates for April and May should we need them. The goal is to present the final written recommendations at the June 12, 2014 CON Commission meeting.

I apologize that I am unable to attend the March 18th meeting to present this update. I will be attending a conference and will not be available. I am comfortable and confident with any of the department staff providing any additional details.

HOSPICE & PALLIATIVE CARE
ASSOCIATION OF MICHIGAN

February 3, 2014

Karen J. Messick, MPA, LNHA
Executive Director
Pilgrim Manor, Inc.
2000 Leonard NE
Grand Rapids, MI 49505
kmessick@pilgrimmanor.org

Certificate of Need Commission
Work Group on Nursing Home Standards

re: Request for Additional Special Pool Beds

Madam Chairwoman:

In 2012/13 when the Nursing Home Standards were under initial review, the Association requested consideration of additional Special Pool Beds for Hospice. Since that initial request, significant changes in reimbursement policy have made an impact on the market and because of that, the Association is no longer recommending an increase in the bed pool.

We appreciate your consideration of our original request as well as the current climate and recommendation of the above.

If you or the Work Group have questions or concerns about the recommendation above, please feel free to contact me.

Regards,

Lisa Ashley, President/CEO

CERTIFICATE OF NEED

1st 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	1st Quarter	Year-to-Date
Approved projects requiring 1-year follow up	87	87
Approved projects contacted on or before anniversary date	58	58
Approved projects completed on or before 1-year follow up	67%	
CON approvals expired	27	27
Total follow up correspondence sent	202	202
Total approved projects still ongoing	383	

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.

- Horizon Management Services, LLC – The Department issued a determination of non-compliance for the central service coordinator (CSC) for providing mobile CT services at a host site that did not receive CON approval at the time the new CT network was initiated. The CSC paid a civil fine of $5,000 and was required to notify all third party payers. A corrective CON application was filed for that host site.

- ProMedica Air – The Department entered into a settlement agreement with this air ambulance provider for replacing the primary air ambulance without CON approval and utilizing back up air ambulances when the primary air ambulance was available. The Settlement was for $60,000 in civil fine and a corrective CON application was filed.

Source: Certificate of Need Evaluation Section, Michigan Department of Community Health.

CERTIFICATE OF NEED

1st 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	1st Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	68	N/A	68	N/A
Letters of Intent Processed within 15 days	68	100%	68	100%
Letters of Intent Processed Online	68	100%	68	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	1st Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	66	N/A	66	N/A
Applications Processed within 15 Days	66	100%	66	100%
Applications Incomplete/More Information Needed	44	67%	44	67%
Applications Filed Online*	59	100%	59	100%
Application Fees Received Online*	15	25%	15	25%

* 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	1st Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	55	100%	55	100%
Substantive Applications	26	100%	26	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	1st 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	1st Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	13	100%	13	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	1st Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	1st Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	26	N/A	26	N/A
FOIA Requests Processed on Time	26	100%	26	100%
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

(03.12.14)

Case Name	Date Opened	Case Description	Status
Medilodge of Livingston v MDCH, et al Macomb County Circuit Court *Livingston – Compare Group* *#95-0214* Includes: *Medilodge of Livingston – CON App # 11-0044* *Livingston Care Center – CON App # 11-0021*	09/14/12	Appeal of the MDCH Director's final decision.	On 4/3/13, the Livingston County Circuit Court transferred the case back to Macomb County. Oral argument was heard on 09/30/13. The Judge took the matter under advisement and will issue a written opinion. The parties stipulated to the filing of the Court of Appeals Order denying the Application for Leave to Appeal issued on 11/1/13 in the Medilodge of Oxford case. This case involved identical issues as in the Oxford case. On December 18, 2013, the Circuit Court affirmed the Department's action and denied the appeal.

CERTIFICATE OF NEED LEGAL ACTION

(03.12.14)

Case Name	Date Opened	Case Description	Status
Medilodge of St. Clair v MDCH, et al St. Clair County Circuit Court *St. Clair – Compare Group* *#95-0217* Includes: *Medilodge of St. Clair – CON App # 11-0032* *Regency on Lk- Ft. Gratiot – CON App # 11-0034*	09/14/12	Appeal of the MDCH Director's final decision.	Oral argument was heard on 9/6/13. Judge took the matter under advisement and will issue a written decision. The parties stipulated to the filing of the Court of Appeals Order denying the Application for Leave to Appeal issued on 11/1/13 in the Medilodge of Oxford case. This case involved identical issues as in the Oxford case. On November 19, 2013, the Circuit Court affirmed the Department's action and denied the appeal.

CERTIFICATE OF NEED LEGAL ACTION

(03.12.14)

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 4/1/13, the Medilodge entities filed an application for leave to appeal with the Michigan Court of Appeals. The Department, Bloomfield Orchard Villa and Manor of Farmington Hills filed responses. 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. The Department, Bloomfield Orchard Villa and Manor of Farmington Hills filed responses in opposition. The Medilodge entities filed a reply brief.

CERTIFICATE OF NEED LEGAL ACTION

(03.12.14)

Case Name	Date Opened	Case Description	Status
Mercy Memorial Nursing Center - CON App # 12-0307	3/11/13	Monroe County – Denial of application seeking nursing home beds – Administrative Appeal	Mercy Memorial amended its application to reduce the number of beds sought and to comply with the existing bed need for the planning area. If MDCH approves the amended application, the matter will be dismissed.
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.	Briefs were filed. Oral Argument held on 12/4/13. Judge took matter under advisement and will issue a written opinion. 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.

CERTIFICATE OF NEED LEGAL ACTION

(03.12.14)

St. Mary's Nursing & Rehab Center, aka St. Mary's Acquisition, Inc. <u>Includes:</u> CON App # 13-0041 and 13-0042 Compare Group: 95-0236	8/26/13	Macomb County – Comparative review of nursing home beds – administrative appeal CON App. #13-0041 (Shelby Nursing Center) was approved for 12 new beds; St. Mary's was denied based on more beds being requested than available.	Prehearing was conducted on 11/21/13. The ALJ will issue a scheduling order for filing of motion. The Department filed its Motion to Dismiss on January 24, 2014. On March 27, 2014, St. Mary's withdrew its request for hearing.

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 Q

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*
Air Ambulance Services	•R	•	•R	•	•	•	•	•	•	•	•	• R—	• P	•	• ▲F									
Bone Marrow Transplantation (BMT) Services													• D	•	• R									
Cardiac Catheterization Services**									•	• PC	•	• R— 1	• R P A	• S	• ▲F S	• S	• S ▮	▮	▮	▮	▮	▮	▮	• R—
Computed Tomography (CT) Scanner Services	•R	•	•	•	•	•	•	•	•	•	•	• R—	• P	•	• ▲F									
Hospital Beds									•	• PC	•	• R— 1	• R P A	•	• ▲F R									
Megavoltage Radiation Therapy (MRT) Services/Units**										• PC	•	•	• R A	• S	• S	• S	• S ▮	▮	▮	▮	▮	▮	▮	• R—
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups**	•R	•	•S	•S	•S	•S	•	•	•	•	•	•	•	•	•	•	•	R—	P	•	F▲			
Open Heart Surgery Services	•	•	• R—	•	•	• R—	• P	•	• ▲F	• PC	•	• R— 1	•R P	•	• ▲F									
Positron Emission Tomography (PET) Scanner Services										• PC	•	• R— 1	• R P A	•	• ▲F	•	•	•	•	•	R—	•	P	F▲
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units**	•R	•	•	•	•	•	•	•	• R	•	•	• R— 1	• 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		

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 March 18, 2014

Updated March 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, 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	August 12, 2010	2016
Bone Marrow Transplantation Services	March 22, 2013	2015
Cardiac Catheterization Services	February 27, 2012	2017
Computed Tomography (CT) Scanner Services	February 27, 2012	2016
Heart/Lung and Liver Transplantation Services	September 28, 2012	2015
Hospital Beds	September 28, 2012	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	November 15, 2013	2017
Positron Emission Tomography (PET) Scanner Services	September 28, 2012	2017
Psychiatric Beds and Services	March 22, 2013	2015
Surgical Services	February 27, 2012	2017
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	February 25, 2008	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.