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

Tuesday, March 27, 2018

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

APPROVED MINUTES

I. Call to Order & Introductions

Chairperson Mittlebrun called the meeting to order at 9:36 a.m. and introduced of Commissioner McKenzie.

A. Members Present:

Thomas Mittelbrun, Chairperson
Denise Brooks-Williams
Gail J. Clarkson, RN
James B. Falahee, Jr., JD
Tressa Gardner
Debra Guido-Allen, RN
Robert Hughes
Melanie LaLonde
Amy McKenzie, MD
Luis Tomatis, MD

B. Members Absent:

None.

C. Department of Attorney General Staff:

Joseph Potchen

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

Tulika Bhattacharya
Matt Lori
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Brooks-Williams, seconded by Commissioner Falahee to approve the agenda as presented. Motion carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of February 8, 2018

Motion by Commissioner Tomatis, seconded by Commissioner Brooks-Williams, to approve the minutes as presented. Motion carried.

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

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

A. Public Comment

1. John Shaski, Sparrow Health System

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Clarkson to take final action on the language (Attachment B) as presented and move forward to the Joint Legislative Committee (JLC) and Governor for the 45-day review period. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

VI. Bone Marrow Transplantation (BMT) Services – Draft Language

Ms. Rogers gave an overview of the draft language (Attachment C).

A. Public Comment

1. Melissa Cupp, RWC Advocacy (see Attachment D for proposed revised language)
2. Joseph Uberti, MD, Karmanos
3. Phillip Stella, MD, Trinity Health
4. Arlene Elliott, Trinity Health
5. Stacy Leick, Economic Alliance of Michigan (EAM)

6. Greg Yanik, MD, University of Michigan (U of M)
7. Stephanie Williams, Spectrum Health
8. Tim O'Rourke, Cancer & Hematology Centers of West Michigan
9. Malcom Henoch, Beaumont Health
10. Sean Gehle, Ascension Michigan
11. Patrick O'Donovan, Beaumont Health

B. Discussion followed.

C. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner Falahee to take proposed action (Attachment C) including the proposed amended language (Attachment D) and move forward for Public Hearing and to the JLC as well as seat a standard advisory committee (SAC) for additional review. Motion failed in a vote of 4 - Yes, 4 - No, and 2 - Abstained.

Motion by Commissioner Falahee, seconded by Commissioner Clarkson to seat a SAC to review if cellular therapies such as CAR-T should be considered for regulation under CON. Delegate development and approval of the charge and seating of the SAC, to the Chairperson of the Commission. Motion carried in a vote of 8 - Yes, 1 - No, and 1 - Abstained.

Recessed at 11:10 a.m. and reconvened at 11:22 a.m.

VII. Cardiac Catheterization Standard Advisory Committee (CCSAC) – Final Report & Draft Language

CCSAC Chairperson Shukri David, MD provided the report and presentation (see Attachment E).

A. Public Comment

1. Alice Betz, MI Chapter American College of Cardiology
2. Tracey Deitz, Henry Ford Health System
3. David Walker, Spectrum Health

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Gardner to take proposed action on the language as presented (Attachment E) and move forward for Public Hearing and to the JLC seeking input on the

replacement language. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

VIII. Nursing Home and Hospital Long-Term-Care Unit (NH-HLTCU) Beds – Re-calculation of Bed Need Numbers – Setting the Effective Date

Paul Delamater provided an updated written report and Ms. Rogers provided an overview (Attachment F).

Public Comment

1. Pat Andersen, Health Care Association of Michigan (HCAM)

Motion by Commissioner Clarkson, seconded by Commissioner Guido-Allen to postpone indefinitely the setting of the effective date of the new bed need numbers and establish a SAC in 2019 to review the methodology with Dr. Delamater. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

IX. Open Heart Surgery Services – Draft Language

Ms. Rogers gave an overview of the draft language (Attachment G).

A. Public Comment

1. Tracey Deitz, Henry Ford Health System
2. David Walker, Spectrum Health
3. Stacy Leick, EAM
4. Marlena Hendershot, Sparrow Health System

B. Discussion followed.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Clarkson to take proposed action on the language (Attachment G) as presented and move forward for Public Hearing and to the JLC with specific requests for mileage vs planning area and why. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

X. Hospital Beds Standard Advisory Committee (HBSAC) – Final Report & Draft Language

HBSAC Chairperson Renee Turner-Bailey provided the report and presentation (see Attachments H and I).

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Hughes to take proposed action on the language as presented (Attachment J) and move forward for Public Hearing and to the JLC. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

XI. 10-Minute Presentation regarding St. Pio's Hospital Model

Mr. Palazzolo with Catholic Healthcare International provided a presentation (Attachment K). Reverend Earl Boyea, Bishop of the Diocese of Lansing, also provided comment.

XII. Legislative Report

None.

XIII. Administrative Update

A. Planning & Access to Care Section Update

Ms. Nagel provided an update.

B. CON Evaluation Section Update

Ms. Bhattacharya provided an update on the following items:

1. Compliance Report (Attachment L)
2. Quarterly Performance Measures (Attachment M)

XIV. Legal Activity Report

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

XV. Future Meeting Dates: June 14, 2018, September 20, 2018, & December 6, 2018

XVI. Public Comment

None.

XVII. Review of Commission Work Plan

Ms. Rogers provided an overview of the changes to the Work Plan (Attachment N).

A. Commission Discussion

None.

B. Commission Action

Motion by Commissioner Clarkson, seconded by Commissioner Guido-Allen to accept the Work Plan as presented with updates from today's meeting. Motion carried in a vote of 10 - Yes, 0- No, and 0- Abstained.

XVIII. Election of Officers

Motion by Commissioner Mittlebrun, seconded by Commission Hughes, to nominate and elect Commissioner Falahee as the Chairperson of the Commission. Motion Carried in a vote of 10 – Yes, 0 – No and 0 – Abstained.

Motion by Commissioner Brooks-Williams, seconded by Commissioner Hughes, to nominate and elect Commissioner Mittelbrun as the Vice-chairperson of the Commission. Motion Carried in a vote of 10 – Yes, 0 – No and 0 – Abstained.

XIX. Adjournment

Motion by Commissioner Brooks-Williams, seconded by Commissioner Guido-Allen, to adjourn the meeting at 12:52 p.m. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

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

Date: February 6, 2018

TO: The Certificate of Need (CON) Commission

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

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

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the UESWL Services Standards at its December 7, 2017 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed UESWL Services Standards on January 25, 2018. Written testimony was accepted for an additional seven days after the hearing. Testimony was received from two individuals.

Written Testimony:

1.) Chuck Mueller, representing self

- Recommends improved access for UESWL.

2.) John Shaski, Sparrow Hospital

- Supports the language as passed at the December Commission meeting.

Department Recommendation:

The Department supports the language as presented at the December 7, 2017 CON Commission meeting.

MICHIGAN DEPARTMENT OF ~~COMMUNITY~~ HEALTH AND HUMAN SERVICES

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

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

Section 1. Applicability

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

Section 2. Definitions

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

(a) "Central service coordinator" OR "CSC" means the organizational unit that has operational responsibility for a mobile UESWL service and its unit(s) and that is a legal entity authorized to do business in the state of Michigan.

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

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

(d) "Complicated stone disease treatment capability" means the expertise necessary to manage all patients during the treatment of kidney stone disease. This includes, but is not limited to:

(i) A urology service that provides skilled and experienced ureteroscopic stone removal procedures and

(ii) Experienced interventional radiologic support.

(e) "Department" means the Michigan Department of ~~Community~~ Health AND HUMAN SERVICES (~~MDCH~~MDHHS).

(f) "Existing mobile UESWL unit" means a CON-approved and operational UESWL unit and transporting equipment operated by a central service coordinator that provides UESWL services to two or more host sites.

(g) "Existing UESWL service" means the utilization of a CON-approved and operational UESWL unit(s) at one site in the case of a fixed UESWL service or at each host site in the case of a mobile UESWL service.

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

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

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

(k) "Licensed site" means either of the following:

(i) In the case of a single site health facility, the location of the facility authorized by license and listed on that licensee's Certificate of Licensure.

(ii) In the case of a health facility with multiple sites, the location of each separate and distinct health facility as authorized by license and listed on that licensee's Certificate of Licensure.

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

(m) "Mobile UESWL unit" means a UESWL unit and transporting equipment operated by a central service coordinator that provides UESWL services to two or more host sites.

(n) "Planning area" means the state of Michigan.
(o) “Region” means the geographic areas set forth in Appendix B.
(p) “Renewal of a lease” means extending the effective period of a lease for an existing UESWL unit that does not involve either the replacement/upgrade of a UESWL unit, as defined in Section 4, or a change in the parties to the lease.
(q) “Retreatment” means a UESWL procedure performed on the same side of the same patient within 6 months of a previous UESWL procedure performed at the same UESWL service. In the case of a mobile service, the term includes a retreatment performed at a different host site if the initial treatment was performed by the same service.
(r) "Ureteroscopic stone removal procedure" means a stone removal procedure conducted in the ureter by means of an endoscope that may or may not include laser technology.
(s) "Urinary extracorporeal shock wave lithotripsy" or "UESWL" means a procedure for the removal of kidney stones that involves focusing shock waves on kidney stones so that the stones are pulverized into sand-like particles, which then may be passed through the urinary tract.
(t) “UESWL service” means either the CON-approved utilization of a UESWL unit(s) at one site in the case of a fixed UESWL service or at each host site in the case of a mobile UESWL service.
(u) "UESWL unit" means the medical equipment that produces the shock waves for the UESWL procedure.

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

Section 3. Requirements to initiate a urinary extracorporeal shock wave lithotripsy service

Sec. 3. Initiate a UESWL service means to begin operation of a UESWL unit, whether fixed or mobile, at a site that does not offer (or has not offered within the last consecutive 12-month period) approved UESWL services. The term does not include the acquisition or replacement of an existing UESWL service or the renewal of a lease.

(1) An applicant proposing to initiate a UESWL service shall demonstrate each of the following:
(a) The capability to provide complicated stone disease treatment on-site.
(b) At least 1,000 procedures are projected pursuant to the methodology set forth in Section 10(1).
(c) The proposed UESWL service shall be provided at a site that provides, or will provide, each of the following:
(i) On-call availability of an anesthesiologist and a surgeon.
(ii) On-site Advanced Cardiac Life Support (ACLS)-certified personnel and nursing personnel.
(iii) EITHER ~~On~~on-site OR THROUGH A CONTRACTUAL AGREEMENT WITH ANOTHER HEALTH FACILITY, 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) EITHER ~~O~~on-site OR THROUGH A CONTRACTUAL AGREEMENT WITH ANOTHER HEALTH FACILITY, A 23-hour holding unit.

(2) AN APPLICANT PROPOSING TO INITIATE A FIXED UESWL SERVICE THAT MEETS THE FOLLOWING REQUIREMENTS SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH SUBSECTION (1)(B):
(a) THE APPLICANT HOSPITAL IS CURRENTLY AN EXISTING MOBILE UESWL HOST SITE.
(b) THE APPLICANT HOSPITAL HAS PERFORMED AN AVERAGE OF AT LEAST 500 PROCEDURES ANNUALLY FOR THE PAST THREE YEARS PRIOR TO SUBMITTING AN APPLICATION.

(c) THE APPLICANT HOSPITAL OPERATES AN EMERGENCY ROOM THAT PROVIDES 24-HOUR EMERGENCY CARE SERVICES AND AT LEAST 80,000 VISITS WITHIN THE MOST RECENT 12-MONTH PERIOD FOR WHICH DATA, VERIFIABLE BY THE DEPARTMENT, IS AVAILABLE.

(d) THE APPLICANT HOSPITAL SHALL INSTALL AND OPERATE THE FIXED UESWL UNIT AT THE SAME SITE AS THE EXISTING HOST SITE.

(e) THE APPLICANT HOSPITAL SHALL CEASE OPERATION AS A HOST SITE AND NOT BECOME A HOST SITE FOR AT LEAST 12 MONTHS FROM THE DATE THE FIXED SERVICE BECOMES OPERATIONAL.

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

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

(1) "Upgrade an existing UESWL unit" means any equipment change, other than a replacement, that involves a capital expenditure of $125,000 or less in any consecutive 24-month period.

(2) An applicant proposing to replace an existing UESWL unit(s) shall demonstrate ~~the following:~~

~~(a) Each existing UESWL unit of the service proposing to replace a UESWL unit has averaged at least 1,000 UESWL procedures per unit during the most recent continuous 12-month period for which the Department has verifiable data.~~

~~(b) Each UESWL unit of the service proposing to replace a UESWL unit is projected to perform at least 1,000 UESWL procedures per unit per year pursuant to the methodology set forth in Section 10.~~

~~(3) An applicant proposing to replace a UESWL unit shall demonstrate~~ one or more of the following:

(a) The existing equipment clearly poses a threat to the safety of the public.

(b) The proposed replacement UESWL unit offers technological improvements that enhance quality of care, increase efficiency, or reduce operating costs and patient charges.

(c) The existing equipment is fully depreciated according to generally accepted accounting principles.

(~~4~~3) An applicant ~~that demonstrates that it meets the requirements in this subsection shall not be required to demonstrate compliance with Section 4(2):~~

~~(a) The proposed project involves replacing~~PROPOSING TO REPLACE 1 existing fixed UESWL unit with 1 mobile UESWL unit SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING~~.~~:

(~~b~~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) The proposed mobile unit will serve at least 1 host site that is located in a region other than the region in which the fixed UESWL unit proposed to be replaced is located currently.

(c) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposed to operate when the results of the methodology in Section 10 are combined for the following, as applicable:

(i) All licensed hospital sites committing MIDB data pursuant to Section 11, as applicable, that are located in the region identified in subsection (c).

(ii) All sites that receive UESWL services from an existing UESWL service and propose to receive UESWL services from the proposed mobile unit and that are located in the region identified in subsection (c).

(d) A separate application from each host site is filed at the same time the application to replace a fixed unit is submitted to the Department.

(e) The proposed mobile UESWL unit is projected to perform at least 1,000 procedures annually pursuant to the methodology set forth in Section 10.

(~~5~~4) An applicant proposing to ~~relocate~~ REPLACE ~~its~~ AN existing FIXED UESWL service and its unit(s) TO A NEW SITE shall demonstrate that the proposed project meets all of the following:

(a) ~~The UESWL service and its unit(s) to be relocated is a fixed UESWL unit(s).~~

~~(b)~~ The UESWL service to be ~~relocated~~ REPLACED has been in operation for at least 36 months as of the date an application is submitted to the Department UNLESS THE APPLICANT MEETS THE REQUIREMENT IN SUBSECTION (d)(i) OR (ii).

(~~c~~b) The site to which the UESWL service will be ~~relocated~~ REPLACED meets the requirements of Section 3(1)(c).

(~~d~~c) The proposed new site is in the state of Michigan and within a 25-mile radius of the existing site of the UESWL service to be ~~relocated~~REPLACED.

(~~e~~d) The UESWL service and its unit(s) to be ~~relocated~~ REPLACED performed an average of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data UNLESS ONE OF THE FOLLOWING REQUIRMENTS ARE MET:~~.~~

(i) THE OWNER OF THE BUILDING WHERE THE SITE IS LOCATED HAS INCURRED A FILING FOR BANKRUPTCY UNDER CHAPTER SEVEN (7) WITHIN THE LAST THREE YEARS;

(ii) THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL; OR

(iii) THE UESWL SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF AN ENTIRE HOSPITAL TO A NEW GEOGRAPHIC SITE AND HAS ONLY ONE (1) UESWL UNIT.

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

(~~6~~5) An applicant proposing to ~~relocate~~ REPLACE a fixed UESWL unit(s) of an existing UESWL service shall demonstrate that the proposed project meets all of the following:

(a) The existing UESWL service from which the UESWL unit(s) is to be ~~relocated~~ REPLACED has been in operation for at least 36 months as of the date an application is submitted to the Department.

(b) The site to which the UESWL unit(s) will be ~~relocated~~ REPLACED meets the requirements of Section 3(1)(c).

(c) The proposed new site is in the state of Michigan and within a 25-mile radius of the existing site of the fixed UESWL unit to be ~~relocated~~REPLACED.

(d) Each existing UESWL unit(s) at the service from which a unit is to be ~~relocated~~ REPLACED performed at least an average of 1,000 procedures per fixed unit in the most recent 12-month period for which the Department has verifiable data.

(e) The applicant agrees to operate the UESWL unit(s) in accordance with all applicable project delivery requirements set forth in Section 9 of these Standards.

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

(~~7~~6) Equipment that is replaced shall be removed from service and disposed of or rendered considerably inoperable on or before the date that the replacement equipment becomes operational.

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

Sec. 5. Expand an existing UESWL service means the addition of one UESWL unit at an existing UESWL service. An applicant proposing to expand an existing UESWL service, whether fixed or mobile, unless otherwise specified, shall demonstrate the following:

(1) All of the applicant's existing UESWL units, both fixed and mobile, at the same geographic location as the proposed additional UESWL unit, have performed an average of at least 1,800 procedures per UESWL unit during the most recent 12-month period for which the Department has verifiable data. In computing this average, the Department will divide the total number of UESWL procedures performed by

the applicant's total number of UESWL units, including both operational and approved but not operational fixed and mobile UESWL units.

(2) The applicant shall project an average of at least 1,000 procedures for each existing and proposed fixed and mobile UESWL unit(s) as a result from the application of the methodology in Section 10 of these standards for the second 12-month period after initiation of operation of each additional UESWL unit whether fixed or mobile.

(3) An applicant proposing to expand an existing mobile UESWL service must provide a copy of the existing or revised contracts between the central service coordinator and each host site(s) that includes the same stipulations as specified in Section 7(1)(c).

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

Sec. 6. Acquisition of an existing UESWL service or existing UESWL unit(s)" means obtaining possession or control of an existing fixed or mobile UESWL service or existing UESWL unit(s) by purchase, lease, donation, or other comparable arrangement.

(1) ~~An~~ THE applicant ~~proposing to acquire an existing fixed or mobile UESWL service and its unit(s)~~ shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs ~~demonstrate that A~~IF THE proposed project meets ~~all~~ ONE of the following:

(a) ~~For an application for the proposed~~IT IS THE first acquisition of ~~an~~ THE existing fixed or mobile UESWL service~~,~~ for which a final decision has not been issued after May 2, 1998~~, an existing UESWL service to be acquired shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs~~. ~~The UESWL service and its unit(s) shall be operating at the applicable volume requirements set forth in Section 9 of these standards in the second 12 months after the date the service and its unit(s) is acquired, and annually thereafter.~~

(b) THE EXISTING FIXED OR MOBILE UESWL SERVICE IS OWNED BY, IS UNDER COMMON CONTROL OF, OR HAS A COMMON PARENT AS THE APPLICANT, AND THE UESWL SERVICE SHALL REMAIN AT THE SAME SITE.

(2) For any application for proposed acquisition of an existing fixed or mobile UESWL service, except ~~the first~~ AN application approved pursuant to subsection (~~a~~1), ~~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~~3) An applicant proposing to acquire an existing fixed or mobile UESWL unit(S) of an existing UESWL service shall demonstrate that the proposed project meets all of the following:

(a) For any application for proposed acquisition of an existing fixed or mobile UESWL unit(s), an applicant shall be required to demonstrate that the UESWL unit(s) to be acquired performed an average of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data.

(b) The requirements of Section 3(1)(c) have been met.

(4) The UESWL service and its unit(s) shall be operating at the applicable volume requirements set forth in Section 9 of these standards in the second 12 months after the date the service and its unit(s) is acquired, and annually thereafter.

Section 7. Additional requirements for approval for mobile UESWL services

Sec. 7. (1) An applicant proposing to begin operation of a mobile UESWL service in Michigan shall demonstrate that it meets all of the following:

(a) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposing to operate when the results of the methodology in Section 10 are combined for the following, as applicable:

(i) All licensed hospital sites committing MIDB data pursuant to Section 11, as applicable, that are located in the region identified in subsection (b).

(ii) All sites that receive UESWL services from an existing UESWL unit and propose to receive UESWL services from the proposed mobile unit are located in the region(s) identified in subsection (b).

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

(2) The requirements of sections 3, 4, and subsection (1)(a) shall not apply to an applicant that proposes to add a Michigan site as a host site if the applicant demonstrates that the mobile UESWL service and its unit(s) operates predominantly outside of Michigan and all of the following requirements are met:

(a) The proposed host site is located in a rural or micropolitan statistical area county.

(b) All existing and approved Michigan UESWL service and its unit(s) locations (whether fixed or mobile) are in excess of 50 miles from the proposed host site and within a region currently served by a UESWL mobile service operating predominantly outside of Michigan.

(c) A separate CON application has been submitted by the CSC and each proposed host site.

(3) A central service coordinator proposing to add, or an applicant proposing to become, a host site on either an existing or a proposed mobile UESWL service shall demonstrate that it meets the requirements of Section 3(1)(C).

~~(4) A central service coordinator proposing to add, or an applicant proposing to become, a host site on an existing mobile UESWL service in a region not currently served by that service shall demonstrate that at least 100 UESWL procedures are projected in each region in which the existing mobile UESWL service is proposing to add a host site when the results of the methodology in Section 10 are combined for the following, as applicable:~~

~~(a) All licensed hospital sites committing MIDB data pursuant to Section 11, as applicable, are located in that region(s).~~

~~(b) All sites that receive UESWL services from an existing UESWL service and its unit(s) and propose to receive UESWL services from the proposed mobile service and its unit(s) are located in that region(s).~~

Section 8. Requirements for Medicaid participation

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

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

Sec 9. An applicant shall agree that, if approved, UESWL services, including all existing and approved UESWL units, shall be delivered in compliance with the following:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) The medical staff and governing body shall receive and review at least annual reports describing activities of the UESWL service, including complication rates, morbidity data, and retreatment rates.

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

(c) An applicant shall develop and utilize a standing medical staff and governing body rule that provides for the medical and administrative control of the ordering and utilization of UESWL services.

(d) An applicant shall require that each urologist serving as a UESWL surgeon shall have completed an approved training program in the use of the lithotripter at an established facility with UESWL services.

(e) An applicant shall establish a process for credentialing urologists who are authorized to perform UESWL procedures at the applicant facility. This shall not be construed as a requirement to establish specific credentialing requirements for any particular hospital or UESWL site.

(f) A urologist who is not an active medical staff member of an applicant facility shall be eligible to apply for limited staff privileges to perform UESWL procedures. Upon request by the Department, an applicant shall provide documentation of its process that will allow a urologist who is not an active medical staff member to apply for medical staff privileges for the sole and limited purpose of performing UESWL procedures. In order to be granted staff privileges limited to UESWL procedures, a urologist shall demonstrate that he or she meets the same requirements, established pursuant to the provisions of subsection (e), that a urologist on an applicant facility's active medical staff must meet in order to perform UESWL procedures.

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

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

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

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

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

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

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

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

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

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

(a) Each UESWL unit, whether fixed or mobile, shall perform at least an average of 1,000 procedures per unit per year in the second 12 months of operation and annually thereafter. The central service coordinator shall demonstrate that a mobile UESWL unit approved pursuant to these standards performed at least 100 procedures in each region that is served by the mobile unit. For purposes of this requirement, the number of UESWL procedures performed at all host sites in the same region shall be combined.

(b) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information; operating schedules; and demographic, diagnostic, morbidity and mortality information; primary diagnosis code; whether the procedure was a first or retreatment UESWL procedure; what other treatment already has occurred; outpatient or inpatient status; complications; and whether follow-up procedures (e.g., percutaneous nephrotomy) were required, as well as the volume of care provided to patients from all payor sources. An applicant shall provide the required data on a separate basis for each host site or licensed site in a format established by the Department and in a mutually-agreed-upon media. The Department may elect to verify the data through on-site review of appropriate records.

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

(5) Compliance with the following mobile UESWL requirements, if applicable:

(a) The volume of UESWL procedures performed at each host site shall be reported to the Department by the central service coordinator.

(b) An applicant with an approved CON for a mobile UESWL service shall notify the Department and the local CON review agency, if any, at least 30 days prior to dropping an existing host site.

(c) Each mobile UESWL service shall establish and maintain an Operations Committee consisting of the central service coordinator's medical director and members representing each host site and the central service coordinator. This committee shall oversee the effective and efficient use of the UESWL unit, establish the normal route schedule, identify the process by which changes are to be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile UESWL service and its unit(s) on at least a quarterly basis.

(d) The central service coordinator shall arrange for emergency repair services to be available 24 hours each day for the mobile UESWL unit equipment and the vehicle transporting the equipment.

(e) If the host site will not be performing the lithotripsy procedures inside the facility, it must provide a properly prepared parking pad for the mobile UESWL unit of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host site also must provide the capability for maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host site to provide for immediate notification of emergency medical situations.

(f) A mobile UESWL service shall operate under a contractual agreement that includes the provision of UESWL services at each host site on a regularly scheduled basis.

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

Section 10. Methodology for projecting UESWL procedures

Sec. 10. (1) The methodology set forth in this subsection shall be used for projecting the number of UESWL procedures at a site or sites that do not provide UESWL services as of the date an application is submitted to the Department. In applying the methodology, actual inpatient discharge data, as specified in the most recent Michigan Inpatient Database available to the Department on the date an application is deemed complete shall be used for each licensed hospital site for which a signed data commitment form has been provided to the Department in accordance with the provisions of Section 11. In applying inpatient discharge data in the methodology, each inpatient record shall be used only once and the following steps shall be taken in sequence:

(a) The number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM codes 592.0, 592.1, or 592.9 (see Appendix D for ICD-10-CM Codes) shall be counted.

(b) The result of subsection (a) shall be multiplied by the factor specified in Appendix A for each licensed hospital site that is committing its inpatient discharge data to a CON application. If more than one licensed hospital site is committing inpatient discharge data in support of a CON application, the products from the application of the methodology for each licensed hospital site shall be summed.

(c) The result of subsection (b) is the total number of projected UESWL procedures for an application that is proposing to provide fixed or mobile UESWL services at a site, or sites in the case of a mobile service, that does not provide UESWL service, either fixed or mobile, as of the date an application is submitted to the Department.

(2) For a site or sites that provide UESWL services as of the date an application is submitted to the Department, the actual number of UESWL procedures performed at each site, during the most recent continuous 12-month period for which the Department has verifiable data, shall be the number used to project the number of UESWL procedures that will be performed at that site or sites.

(3) For a proposed UESWL unit, except for initiation, the results of subsections (1) and (2), as applicable, shall be summed and the result is the projected number of UESWL procedures for the proposed UESWL unit for purposes of the applicable sections of these standards.

(4) An applicant that is projecting UESWL procedures pursuant to subsection (1) shall provide access to verifiable hospital-specific data and documentation using a format prescribed by the Department.

Section 11. Requirements for MIDB data commitments

Sec. 11. (1) In order to use MIDB data in support of an application for UESWL services, an applicant shall demonstrate or agree to, as applicable, all of the following.

(a) A licensed hospital site whose MIDB data is used in support of a CON application for a UESWL service shall not use any of its MIDB data in support of any other application for a UESWL service for 5 years following the date the UESWL service to which the MIDB data are committed begins to operate. The licensed hospital site shall be required to commit 100% of its inpatient discharge data to a CON application.

(b) The licensed hospital site, or sites, committing MIDB data to a CON application has completed the departmental form(s) that agrees to or authorizes each of the following:

(i) The Michigan Health and Hospital Association may verify the MIDB data for the Department.

(ii) An applicant shall pay all charges associated with verifying the MIDB data.

(iii) The commitment of the MIDB data remains in effect for the period of time specified in subsection (1)(a).

(c) A licensed hospital site that is proposing to commit MIDB data to an application is admitting patients regularly as of the date the director makes the final decision on that application under Section 22231(9) of the Code, being Section 333.22231(9) of the Michigan Compiled Laws.

(2) The Department shall consider an MIDB data commitment in support of an application for a UESWL service from a licensed hospital site that meets all of the following:

(a) The licensed hospital site proposing to commit MIDB data to an application does not provide, or does not have a valid CON to provide, UESWL services, either fixed or mobile, as of the date an application is submitted to the Department.

(b) The licensed hospital site proposing to commit MIDB data is located in a region in which a proposed fixed UESWL service is proposed to be located or, in the case of a mobile unit, has at least one host site proposed in that region.

(c) The licensed hospital site meets the requirements of subsection (1), as applicable.

Section 12. Effect on prior planning policies; comparative reviews

Sec. 12. (1) These CON review standards supersede and replace the CON review standards for urinary extracorporeal shock wave lithotripsy (UESWL) services approved by the CON Commission on ~~March 18~~SEPTEMBER 25, 2014 and effective on ~~June~~ DECEMBER 22, 2014.

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

APPENDIX A

Factor For Calculating Projected UESWL Procedures

(1) Until changed by the Department, the factor to be used in Section 10(1)(b) used for calculating the projected number of UESWL procedures shall be 1.~~09~~104.

(2) The Department may amend Appendix A by revising the factor in subsection (1) in accordance with the following steps:

(a) Steps for determining statewide UESWL adjustment factor:

(i) Determine the total statewide number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM codes 592.0, 592.1, or 592.9 (see Appendix D for ICD-10-CM Codes) for the most recent year for which Michigan Inpatient Database information is available to the Department.

(ii) Determine the total number of UESWL procedures performed in the state using the Department's Annual Hospital Questionnaire for the same year as the MIDB being used in subsection (i) above.

(iii) Divide the number of UESWL procedures determined in subsection (ii) above by the number of inpatient records determined in subsection (i) above.

(b) Steps for determining "urban/rural" adjustment factor:

(i) For each hospital, assign urban/rural status based on the ~~2000 census~~COUNTY CLASSIFICATIONS FOUND IN APPENDIX C. "Metropolitan statistical area counties" will be assigned "urban" status, and "micropolitan statistical area" and "rural" counties will be assigned "rural" status.

(ii) Aggregate the records from step (a)(i) by zip code "urban/rural" status.

(iii) Identify the zip codes in which all records are either "urban" status or "rural" status. Aggregate the number of records and zip code populations separately by "urban/rural" status.

(iv) For zip codes having records in both "urban" and "rural" status, Calculate the proportion of records in "urban" and "rural" by dividing the respective number of records by the total number of records for that zip code. Multiply the population of each zip code by its respective "urban" and "rural" proportions.

(v) Aggregate the records and populations from step (b)(iv) separately by "urban/rural" status.

(vi) The sub-totals from step (v) will then be added to the sub-totals from step (iii) to produce totals for "urban" & "rural" separately. Calculate the "urban" and "rural" discharge rates per 10,000 (DRU and DRR, respectively) by dividing the total number of records by the total population for each status, then multiplying by 10,000.

(vii) Divide the urban discharge rate by the rural discharge rate (DRU/DRR) to calculate the "urban/rural" adjustment factor. Multiply the statewide adjustment factor identified in step (a)(iii) by the "urban/rural" adjustment factor. The result is the revised factor for calculating UESWL procedures.

(3) The Department shall notify the Commission when this revision is made and the effective date of the revision.

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
	Menominee	Ontonagon	Schoolcraft	

APPENDIX C

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

APPENDIX 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 AND HUMAN SERVICES

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. THE TERM INCLUDES THE FOLLOWING CELLULAR THERAPY PRODUCTS: CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELLS, NATURAL KILLER (NK) CELLS, DENDRITIC CELLS, MESENCHYMAL CELLS, AND GENE THERAPY PRODUCTS DERIVED FROM HEMATOPOIETIC STEM CELLS WHEN USED TO TREAT A HEMOTOLOGICAL MALIGNANCY.

(e) "Cancer hospital" means a hospital that is a Comprehensive Cancer Center designated by the National Cancer Institute or operates a Comprehensive Cancer Center as an affiliate of a Michigan university that is designated as a Comprehensive Cancer Center by the National Cancer Institute.

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

(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 AND HUMAN SERVICES (~~MDCH~~MDHHS).

(j) "Department inventory of BMT services" means the list maintained by the Department of: (i) the bone marrow transplantation services operating pursuant to a valid CON issued under Part 222 or former

Part 221; (ii) operating BMT services for which the operation of that service did not require a CON; and (iii) BMT services that are not yet operational but have a valid CON issued under Part 222. The list shall inventory adult and pediatric services separately and shall specify the site at which the BMT service is authorized.

(k) "Existing BMT service," for purposes of Section 3(5) AND 3(11) 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, AND AN EXISTING ADULT OR PEDIATRIC BMT SERVICE THAT IS PROPOSING TO PROVIDE ADDITIONAL CELLULAR THERAPY PRODUCTS NOT PREVIOUSLY APPROVED FOR UNDER THESE STANDARDS. 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).

(11) AN APPLICANT PROPOSING TO INITIATE A BMT SERVICE THAT IS TO PROVIDE ADDITIONAL CELLULAR THERAPY PRODUCTS NOT PREVIOUSLY APPROVED FOR UNDER THESE STANDARDS SHALL DEMONSTRATE THE FOLLOWING:
(a) THE APPLICANT IS AN EXISTING ADULT OR PEDIATRIC BMT SERVICE THAT IS MEETING VOLUME THE REQUIREMENTS IN SECTION 7(4).
(b) SUCH AN APPLICATION SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW AND SHALL BE PROCESSED UNDER THE PROCEDURES FOR NON-SUBSTANTIVE REVIEW.
(c) AN APPLICANT AGREES AND ASSURES TO COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS.

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.
(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.

(2) An applicant approved for and holding a CON for BMT services under this section prior to the effective date of this revision of the BMT standards, September 29, 2014, shall apply to reacquire the BMT service, and the acquired BMT service shall be accountable under these revised standards.

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

Section 5. Review standards for comparative reviews

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

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

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

Straight-line Distance 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 ~~December 13, 2012~~JUNE 12, 2014 and effective on ~~March 22, 2013~~SEPTEMBER 29, 2014.

(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

Attachment D

CON Standards for Bone Marrow Transplantation Services

Proposed Amendment to Definition

3/27/2018

Replace the definition of "Bone marrow transplantation service" or "BMT service" found in Section 2(1)(d) with the following:

(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. THE TERM INCLUDES INFUSIONS OF GENETICALLY MODIFIED PROLIFERATING CELLS WHICH ARE DERIVED FROM THE HEMATOPOIETIC STEM CELL WHICH REQUIRE THE INFRASTRUCTURE, QUALITY, AND SAFETY MEASURES INCORPORATED INTO BMT PROGRAMS. ~~AT PRESENT~~ THIS TERM WILL INCLUDE CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELLS WHEN USED TO TREAT A HEMOTOLOGICAL MALIGNANCY.

Note: Highlighted text indicates difference from Department proposed definition.

MICHIGAN DEPARTMENT OF ~~COMMUNITY~~ HEALTH AND HUMAN SERVICES

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) "ADULT CARDIAC CATHETERIZATION SERVICE" MEANS PROVIDING CARDIAC CATHETERIZATION SERVICES ON AN ORGANIZED, REGULAR BASIS TO PATIENTS AGE 18 AND ABOVE, AND FOR ELECTROPHYSIOLOGY PROCEDURES TO PATIENTS AGE 15 AND OLDER.

(b) "Cardiac catheterization laboratory" or "laboratory" means an individual radiological room equipped with a variety of x-ray machines and devices such as electronic image intensifiers~~, high speed film changers~~ and digital subtraction units to assist in performing diagnostic or therapeutic cardiac catheterizations or electrophysiology studies.

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

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

(e) "CARDIAC CATHETERIZATION SESSION" MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC OR THERAPEUTIC CARDIAC OR PERIPHERAL PROCEDURES IN A CARDIAC CATHETERIZATION LABORATORY. THE TERM SESSION APPLIES TO BOTH ADULT AND PEDIATRIC/CONGENITAL CATHETERIZATIONS.

(~~d~~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.

(~~e~~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) "COMPLEX THERAPEUTIC SESSION" MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT UNDERGOES ONE OR MORE OF THE FOLLOWING PROCEDURES:

(i) PCI FOR CHRONIC TOTAL OCCLUSION

(ii) TAVR, MITRAL/PULMONARY/TRICUSPID VALVE REPAIR OR REPLACEMENT, PARAVALVULAR LEAK CLOSURE

(iii) ABLATION FOR ATRIAL FIBRILLATION (AF) OR VENTRICULAR TACHYCARDIA (VT), PACEMAKER OR ICD LEAD EXTRACTION

(~~f~~i) "Department" means the Michigan Department of ~~Community~~ Health AND HUMAN SERVICES (MD~~C~~HHS).

(j) "DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURE" INCLUDES RIGHT HEART CATHETERIZATION, LEFT HEART CATHETERIZATION, CORONARY ANGIOGRAPHY, CORONARY ARTERY BYPASS GRAFT ANGIOGRAPHY, INTRACORONARY ADMINISTRATION OF DRUGS, FRACTIONAL FLOW RESERVE (FFR), INTRA-CORONARY IMAGING SUCH AS INTRAVASCULAR ULTRASOUND (IVUS), OPTICAL COHERENCE TOMOGRAPHY (OCT), OR NEAR-INFRARED SPECTROSCOPY (NIRS) WHEN PERFORMED WITHOUT A THERAPEUTIC PROCEDURE, CARDIAC BIOPSY, INTRA-CARDIAC ECHOCARDIOGRAPHY, AND ELECTROPHYSIOLOGY STUDY.

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

(l) "DIAGNOSTIC CARDIAC CATHETERIZATION SESSION" MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES.

(m) "DIAGNOSTIC PERIPHERAL PROCEDURE" INCLUDES ANGIOGRAPHY OR HEMODYNAMIC MEASUREMENTS IN THE ARTERIAL OR VENOUS CIRCULATION (EXCLUDING THE HEART).

(n) "DIAGNOSTIC PERIPHERAL SESSION" MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC PERIPHERAL PROCEDURES IN A CARDIAC CATHETERIZATION LABORATORY.

(~~h~~o) "Elective percutaneous coronary intervention (PCI)" means a PCI procedure performed on a non-emergent basis.

(~~i~~p) "Elective PCI services without on-site open heart surgery (OHS)" means performing PCI~~, percutaneous transluminal coronary angioplasty (PTCA), and coronary stent implantation~~ on an organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary PCI service but not having OHS on-site and adhering to patient selection as outlined in the SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site Surgical Backup and published in ~~circulation~~ Circulation 2014, 129:2610-2626 and its update or further guideline changes. *A HOSPITAL THAT PROVIDES ELECTIVE PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM RIGHT-SIDED CARDIAC ABLATION PROCEDURES INCLUDING RIGHT ATRIAL FLUTTER, AV REENTRY, AV NODE REENTRY, RIGHT ATRIAL TACHYCARDIA, AND AV NODE ABLATION.*

(~~j~~q) "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.

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

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

(~~m~~t) "Pediatric/CONGENITAL cardiac catheterization service" means providing cardiac AND ELECTROPHYSIOLOGYcatheterization 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~~ PATIENTS BORN 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)~~.

(u) "PERCUTANEOUS CORONARY INTERVENTION" (PCI) MEANS A THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURE TO RESOLVE ANATOMIC AND/OR PHYSIOLOGIC PROBLEMS IN THE CORONARY ARTERIES OF THE HEART. A PCI SESSION MAY INCLUDE SEVERAL PROCEDURES INCLUDING BALLOON ANGIOPLASTY, ATHERECTOMY, LASER, STENT IMPLANTATION AND THROMBECTOMY. THE TERM DOES NOT INCLUDE THE INTRACORONARY ADMINISTRATION OF DRUGS, FFR OR IVUS WHERE THESE ARE THE ONLY PROCEDURES PERFORMED.

(v) "PERIPHERAL CATHETERIZATION SESSION" MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC OR THERAPEUTIC PROCEDURES IN THE ARTERIAL OR VENOUS CIRCULATION (EXCLUDING THE HEART) WHEN PERFORMED IN A CARDIAC CATHETERIZATION LABORATORY.

(~~n~~w) "Primary percutaneous coronary intervention (PCI)" means a PCI performed on an EMERGENT BASIS ON A ~~acute myocardial infarction (AMI)~~ patient with ~~confirmed~~ ST-SEGMENT elevation, ~~or~~ new left bundle branch block ~~on an emergent basis~~, ECG EVIDENCE OF TRUE POSTERIOR MI, OR CARDIOGENIC SHOCK.

(~~o~~x) "Primary PCI service without on-site OHS" means performing primary PCI on an emergent basis in a hospital having a diagnostic cardiac catheterization service. *A HOSPITAL THAT PROVIDES PRIMARY PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM RIGHT-SIDED CARDIAC ABLATION PROCEDURES INCLUDING RIGHT ATRIAL FLUTTER, AV REENTRY, AV NODE REENTRY, RIGHT ATRIAL TACHYCARDIA, AND AV NODE ABLATION.*

(~~p~~y) "Procedure equivalent" means a unit of measure that reflects the relative average length of time one patient spends in one session in a CARDIAC CATHETERIZATION laboratory ~~*based on the type of procedures being performed*~~. ~~*THIS LENGTH OF TIME MEANS THE PERIOD FROM WHEN THE PATIENT ENTERS ("WHEELS-IN") AND LEAVES ("WHEELS-OUT") THE LABORATORY.*~~ IF A DIAGNOSTIC AND THERAPEUTIC PROCEDURE IS PERFORMED IN THE SAME SESSION, THE HIGHER PROCEDURE EQUIVALENT WEIGHTING WILL BE USED TO EVALUATE UTILIZATION.

(z) "STRUCTURAL HEART PROCEDURE" MEANS A THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURE TO RESOLVE ANATOMIC AND/OR PHYSIOLOGIC PROBLEMS OF THE HEART VALVES OR CHAMBERS. PROCEDURES INCLUDE: BALLOON VALVULOPLASTY, BALLOON ATRIAL SEPTOSTOMY, TRANSCATHETER VALVE REPAIR, TRANSCATHETER VALVE IMPLANTATION, PARAVALULAR LEAK CLOSURE, LEFT ATRIAL APPENDAGE OCCLUSION, PFO/ASD/VSD/PDA CLOSURE, ALCOHOL ABLATION OF CARDIAC TISSUE, EMBOLIZATION OF CORONARY FISTULAE AND ABNORMAL VASCULAR CONNECTIONS IN THE HEART.

(~~q~~aa) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or physiological problems in the heart. ~~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, PTCA with 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.~~

~~(bb) *"THERAPEUTIC CARDIAC CATHETERIZATION SERVICE WITHOUT ON-SITE SURGERY" MEANS PROVIDING ELECTIVE PCI, PRIMARY PCI, PERMANENT PACEMAKER IMPLANTATION, AND ICD IMPLANTATION. A HOSPITAL THAT PROVIDES ELECTIVE OR PRIMARY PCI WITHOUT ON-SITE SURGERY MAY ALSO PERFORM RIGHT-SIDED CARDIAC ABLATION PROCEDURES INCLUDING RIGHT ATRIAL FLUTTER, AV REENTRY, AV NODE REENTRY, RIGHT ATRIAL TACHYCARDIA, AND AV NODE ABLATION.*~~

~~*(cc)*~~ "THERAPEUTIC CARDIAC CATHETERIZATION SESSION" MAY INCLUDE: PCI (ELECTIVE, EMERGENT), PERICARDIOCENTESIS, PERMANENT PACEMAKER IMPLANTATION, ICD IMPLANTATION (ENDOVASCULAR OR SUBCUTANEOUS), PACEMAKER OR ICD GENERATOR CHANGE, PACEMAKER OR ICD LEAD REVISION, CARDIAC ABLATION, AND/OR STRUCTURAL HEART PROCEDURE. THIS ALSO INCLUDES IMPLANTATION OF A CIRCULATORY SUPPORT DEVICE SUCH AS IABP, IMPELLA, ECMO OR TANDEMHEART WHERE THIS IS THE ONLY THERAPEUTIC PROCEDURE. WHEN PCI IS PERFORMED IN MORE THAN ONE CORONARY ARTERY DURING THE SAME SETTING, THIS IS COUNTED AS ONE SESSION.

(dd) "THERAPEUTIC PERIPHERAL PROCEDURE" MEANS A THERAPEUTIC CATHETERIZATION PROCEDURE TO RESOLVE ANATOMIC AND/OR PHYSIOLOGIC PROBLEMS IN THE ARTERIAL OR VENOUS CIRCULATION (EXCLUDING THE HEART). PROCEDURES MAY INCLUDE PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA), ATHERECTOMY, DRUG ELUTING BALLOON, LASER, STENT IMPLANTATION, IVC FILTER IMPLANTATION OR RETRIEVAL, CATHETER-DIRECTED ULTRASOUND/THROMBOLYSIS, AND THROMBECTOMY.

(ee) "THERAPEUTIC PERIPHERAL SESSION" MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE THERAPEUTIC PERIPHERAL PROCEDURES IN A CARDIAC CATHETERIZATION LABORATORY.

(ff) "THERAPEUTIC PEDIATRIC/CONGENITAL CARDIAC CATHETERIZATION SESSION" MAY INCLUDE: STRUCTURAL HEART PROCEDURE (AS LISTED ABOVE), PULMONARY ARTERY ANGIOPLASTY/STENT IMPLANTATION, PULMONARY VALVE PERFORATION, ANGIOPLASTY/STENT IMPLANTATION FOR AORTIC COARCTATION, CARDIAC ABLATION, PACEMAKER/ICD IMPLANTATION, AND PCI.

(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 HOSPITAL proposing to initiate cardiac catheterization services shall demonstrate the following, as applicable to the proposed project.

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

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

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

(b) An applicant HOSPITAL 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 HOSPITAL has applied to provide adult OHS services at the hospital. The applicant HOSPITAL must be approved for an adult OHS service in order to be approved for an adult therapeutic cardiac catheterization service.

(d) The applicant HOSPITAL 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 HOSPITAL proposing to initiate a pediatric/CONGENITAL cardiac catheterization service shall demonstrate the following:

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

(b) The applicant HOSPITAL has standardized biplane equipment as defined in the most current American Academy of Pediatrics (AAP) and American College of Cardiology Foundation (ACCF)/Society for Cardiovascular Angiography and Interventions (SCAI) guidelines for pediatric cardiovascular centers.

(c) The applicant HOSPITAL has on-site pediatric and neonatal ICU as outlined in the most current AAP and ACCF/SCAI guidelines above.

(d) The applicant HOSPITAL has applied to provide pediatric OHS services at the hospital. The applicant HOSPITAL must be approved for a pediatric OHS service in order to be approved for pediatric*/CONGENITAL* cardiac catheterization services.

(e) The applicant HOSPITAL has on-site pediatric extracorporeal membrane oxygenation (ECMO) capability as outlined in the most current ACCF/SCAI guidelines.

(f) A pediatric*/CONGENITAL* cardiac catheterization service shall have a quality assurance plan as outlined in the most current ACCF/SCAI guidelines.

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

Section 4. Requirements to initiate primary or elective PCI Services without on-site OHS services

Sec. 4. An applicant HOSPITAL proposing to initiate primary or elective PCI services without on-site OHS services shall demonstrate the following:

(1) The applicant HOSPITAL 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.

(2) The applicant HOSPITAL has at least two interventional cardiologists to perform the PCI procedures and each cardiologist has performed at least 50 PCI sessions annually as the primary operator during the most recent 24-month period preceding the date the application was submitted to the Department.

(3) 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 OHS hospital; and participate in an un-interrupted 24-hour, 365-day call schedule. Competency shall be documented annually.

(4) 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.

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

(6) A written agreement with an OHS hospital that includes all of the following:

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

(b) Provision for ongoing cross-training for professional and technical staff involved in the provision of PCI to ensure familiarity with interventional equipment. Competency shall be documented annually.
(c) 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 PCI patient candidates. Competency shall be documented annually.
(d) Regularly held joint cardiology/cardiac surgery conferences to include review of all PCI cases.
(e) Development and ongoing review of patient selection criteria for PCI patients and implementation of those criteria.
(f) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for prompt care.
(g) Written protocols, signed by the applicant HOSPITAL and the OHS hospital, for the immediate transfer within 60 minutes travel time from the cardiac catheterization laboratory to evaluation on site in the OHS hospital, of patients requiring surgical evaluation and/or intervention 365 days a year. If the applicant HOSPITAL meets the requirements of subsection (13)(c), then the OHS hospital can be more than 60 minutes travel time from the proposed site. The protocols shall be reviewed and tested on a quarterly basis.
(h) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for the provision of interventional procedures.

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

(8) 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.

(9) At least two physicians credentialed to perform 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 PCI designed to meet the requirements for this certification and in keeping with the current guidelines for the provision of PCI without on-site OHS services promulgated by the American College of Cardiology and American Heart Association.

(10) 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 PCI services without on-site OHS services, and the applicant hospital shall identify a physician point of contact for the data registry.

(11) Cath lab facility requirements and collaborative cardiologists-heart surgeon relationship requirements shall conform to all SCAI/ACC Guidelines for PCI Services Without On-Site OHS including the SCAI/ACC/AHA Expert Consensus Document. The applicant hospital shall be liable for the cost of demonstrating compliance with these criteria in their application.

(12) The applicant HOSPITAL shall project the following based on data from the most recent 12-month period preceding the date the application was submitted to the Department, as applicable.
(a) If the applicant HOSPITAL is applying for a primary PCI service without open heart surgery, the applicant HOSPITAL shall project a minimum of 36 primary PCI procedures per year.
(b) If the applicant HOSPITAL is applying for an elective PCI service without on-site OHS, the applicant HOSPITAL shall project a minimum of 200 PCI procedures per year.

(13) If the applicant HOSPITAL is applying for an elective PCI service without on-site OHS, the applicant HOSPITAL also shall demonstrate the following:
(a) The applicant HOSPITAL operated a primary PCI service for at least one year prior to the date of application.

(b) The applicant HOSPITAL submitted data to a data registry administered by the Department or its designee and been found to have acceptable performance as compared to the registry benchmarks for the most recent 12 months prior to the date of application.

(c) If the applicant HOSPITAL was not approved as a primary PCI service prior to September 14, 2015, then, in addition, the applicant HOSPITAL shall demonstrate that there is no PCI or OHS service within 60 radius miles or 60 minutes travel time from the proposed site.

(14) If the applicant HOSPITAL is currently providing OHS services and therapeutic cardiac catheterization services and is proposing to discontinue OHS services and therapeutic cardiac catheterization services, then the applicant HOSPITAL shall apply to initiate primary or elective PCI services without on-site OHS using this section. The applicant HOSPITAL shall demonstrate all of the requirements in this section except for subsection (13) and is subject to all requirements in Section 10.

Section 5. Requirements to replace an existing cardiac catheterization service or laboratory

Sec. 5. 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 HOSPITAL proposing to replace a cardiac catheterization laboratory or service shall demonstrate the following as applicable to the proposed project:

(1) An applicant HOSPITAL 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 HOSPITAL 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 HOSPITAL 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/*CONGENITAL* 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.

(3) AN APPLICANT HOSPITAL PROPOSING TO REPLACE A CARDIAC CATHETERIZATION SERVICE TO A NEW SITE SIMULTANEOUSLY WITH AN OPEN HEART SURGERY SERVICE SHALL DEMONSTRATE THE FOLLOWING:

(a) THE EXISTING CARDIAC CATHETERIZATION SERVICE TO BE REPLACED HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(b) THE PROPOSED NEW SITE IS A HOSPITAL THAT IS OWNED BY, IS UNDER COMMON CONTROL OF, OR HAS A COMMON PARENT AS THE APPLICANT HOSPITAL.

(c) THE PROPOSED NEW SITE IS THE SAME SITE WHERE THE EXISTING OHS SERVICE IS TO BE LOCATED WHICH IS WITHIN THE SAME PLANNING AREA AS THE OHS SERVICE.

(d) THE EXISTING CARDIAC CATHETERIZATION SERVICE TO BE RELOCATED PERFORMED AT LEAST THE APPLICABLE MINIMUM NUMBER OF CARDIAC CATHETERIZATION CASES SET FORTH IN SECTION 10 AS OF THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT.

Section 6. Requirements to expand a cardiac catheterization service

Sec. 6. An applicant HOSPITAL proposing to add a laboratory to an existing cardiac catheterization service shall demonstrate the following:

(1) The applicant HOSPITAL 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/*CONGENITAL* cardiac catheterization procedures.

(2) The applicant HOSPITAL 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 7. Requirements to acquire a cardiac catheterization service

Sec. 7. 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 HOSPITAL 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 HOSPITAL 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 Section 10. 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 HOSPITAL and annually thereafter.

(c) For any application proposing to acquire an existing cardiac catheterization service, except the first application approved pursuant to subsection (b), an applicant HOSPITAL shall be required to document that the cardiac catheterization service to be acquired is operating in compliance with the

volume requirements set forth in section 10 of these standards applicable to an existing cardiac catheterization service on the date the application is submitted to the Department.

(2) An applicant HOSPITAL 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 8. Requirements for a hybrid operating room/cardiac catheterization laboratory (OR/CCL)

Sec. 8. A hybrid OR/CCL means an operating room located on a sterile corridor and equipped with an angiography system permitting minimally invasive procedures of the heart and blood vessels with full anesthesia capabilities. An applicant HOSPITAL proposing to add one or more hybrid OR/CCLs at an existing cardiac catheterization service shall demonstrate each of the following:

(1) The applicant HOSPITAL operates an OHS service which is in full compliance with the current CON Review Standards for OHS Services.

(2) The applicant operates a therapeutic cardiac catheterization program which is in full compliance with sectionS ~~5~~3(2) AND 10(4) 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 HOSPITAL is in compliance with Section 6 of these standards.

(4) If the hybrid OR/CCL(s) represents conversion of an existing cardiac catheterization laboratory(s), the applicant HOSPITAL is in compliance with the provisions of Section 5, if applicable.

(5) The applicant HOSPITAL 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 9. **Requirement for Medicaid participation**

Sec. 9. An applicant HOSPITAL shall provide verification of Medicaid participation at the time the application is submitted to the Department. An applicant HOSPITAL 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 10. Project delivery requirements and terms of approval for all applicants

Sec. 10. An applicant HOSPITAL 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 DIAGNOSTIC LEFT-HEART CATHETERIZATION AND/OR CORONARY ANGIOGRAPHY MUST PERFORM, AS THE PRIMARY OPERATOR, AN AVERAGE OF AT LEAST 50 DIAGNOSTIC CARDIAC CATHETERIZATION SESSIONS INVOLVING A LEFT-HEART CATHETERIZATION OR CORONARY ANGIOGRAPHY PER YEAR AVERAGED OVER THE MOST RECENT 2 YEARS STARTING IN THE SECOND 12 MONTHS AFTER BEING CREDENTIALED. THIS TWO YEAR AVERAGE WILL BE EVALUATED ON A ROLLING BASIS ANNUALLY THEREAFTER. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS A CARDIAC CATHETERIZATION SESSION IN WHICH THAT PHYSICIAN PERFORMED, AS THE PRIMARY OPERATOR, AT LEAST ONE LEFT-HEART CATHETERIZATION OR CORONARY ANGIOGRAPHY, IN ANY COMBINATION OF HOSPITALS. PHYSICIANS FALLING BELOW THIS VOLUME REQUIREMENT MUST BE PLACED ON A FOCUSED PROFESSIONAL PRACTICE EVALUATION (FPPE) PLAN, WHICH MUST INCLUDE AN INDEPENDENT REVIEW OF ALL DIAGNOSTIC CARDIAC CATHETERIZATION SESSIONS BY AN APPROPRIATE DESIGNEE, TO ENSURE QUALITY OUTCOMES ARE MAINTAINED. IN THE EVENT A PHYSICIAN DOES NOT PERFORM CARDIAC CATHETERIZATION PROCEDURES ON A TEMPORARY OR PERMANENT BASIS FOR A PERIOD OF 3 MONTHS OR MORE, THE PHYSICIAN DIAGNOSTIC PROCEDURE VOLUME WILL BE ANNUALIZED ON THE 24 MONTH PERIOD PRECEDING THE ABSENCE. WHEN A DIAGNOSTIC CARDIAC CATHETERIZATION SESSION AND AD HOC THERAPEUTIC CARDIAC CATHETERIZATION SESSION ARE PERFORMED TOGETHER, DIAGNOSTIC AND THERAPEUTIC SESSIONS ARE COUNTED SEPARATELY FOR THE PURPOSES OF THIS SUBSECTION. IF A PHYSICIAN IS DOING RIGHT HEART ONLY PROCEDURES, THEN THEY ARE NOT REQUIRED TO MEET THIS VOLUME REQUIREMENT. PHYSICIANS WHO ARE CREDENTIALED BY A HOSPITAL TO PERFORM ADULT THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES ARE NOT REQUIRED TO MEET THE VOLUME REQUIREMENT FOR DIAGNOSTIC CARDIAC CATHETERIZATION SESSIONS.

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

(~~e~~f) Each physician credentialed by a hospital to perform pediatric/CONGENITAL cardiac catheterizations shall perform, as the primary operator, aN ~~minimum~~ AVERAGE of AT LEAST 50

pediatric/*CONGENITAL* cardiac catheterization ~~procedures~~ SESSIONS per year AVERAGED OVER THE MOST RECENT 2 YEARS STARTING in the second 12 months after being credentialed. THIS TWO YEAR AVERAGE WILL BE EVALUATED ON A ROLLING BASIS ~~and~~ annually thereafter. The annual case load for a physician means pediatric/*CONGENITAL* cardiac catheterization ~~procedures~~ SESSIONS performed by that physician in any combination of hospitals. PHYSICIANS FALLING BELOW THIS VOLUME REQUIREMENT MUST BE PLACED ON A FOCUSED PROFESSIONAL PRACTICE EVALUATION (FPPE) PLAN, WHICH MUST INCLUDE AN INDEPENDENT REVIEW OF ALL CARDIAC CATHETERIZATION SESSIONS BY AN APPROPRIATE DESIGNEE, TO ENSURE QUALITY OUTCOMES ARE MAINTAINED. IN THE EVENT A PHYSICIAN DOES NOT PERFORM CARDIAC CATHETERIZATION PROCEDURES ON A TEMPORARY OR PERMANENT BASIS FOR A PERIOD OF 3 MONTHS OR MORE, THE PHYSICIAN THERAPEUTIC PROCEDURE VOLUME WILL BE ANNUALIZED ON THE 24 MONTH PERIOD PRECEDING THE ABSENCE.

(~~f~~g) An adult diagnostic cardiac catheterization service shall have a minimum of two ~~appropriately trained~~ physicians on its active hospital staff MEETING THE FOLLOWING CRITERIA~~. 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 catheterization~~s~~ SESSIONS in the preceding 12 months. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS A CARDIAC CATHETERIZATION SESSION IN WHICH THAT PHYSICIAN PERFORMED, AS THE PRIMARY OPERATOR, AT LEAST ONE DIAGNOSTIC CARDIAC CATHETERIZATION, IN ANY COMBINATION OF HOSPITALS.

(~~g~~h) An adult therapeutic cardiac catheterization service shall have a minimum of two ~~appropriately trained~~ physicians on its active hospital staff MEETING THE FOLLOWING CRITERIA~~. 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 50 adult therapeutic cardiac catheterization ~~procedures~~ SESSIONS in the preceding 12 months. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS A CARDIAC CATHETERIZATION SESSION IN WHICH THAT PHYSICIAN PERFORMED, AS THE PRIMARY OPERATOR, AT LEAST ONE THERAPEUTIC CARDIAC CATHETERIZATION, IN ANY COMBINATION OF HOSPITALS.

(~~h~~i) A pediatric/*CONGENITAL* cardiac catheterization service shall have ~~an appropriately trained~~AT LEAST ONE physician on its active hospital staff MEETING THE FOLLOWING CRITERIA~~. 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/*CONGENITAL* cardiac catheterizations; and

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

(~~i~~j) A pediatric/*CONGENITAL* cardiac catheterization service shall maintain a quality assurance plan as outlined in the most current ACCF/SCAI Guidelines.

(~~j~~k) 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 100 catheterizations per year during each of the five preceding years. The Department may accept other evidence that the director is appropriately trained.

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

(~~l~~m) The applicant hospital providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective PCI services without on-site OHS service shall participate with a data registry administered by the Department or its designee that monitors quality and risk adjusted outcomes.

(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/*CONGENITAL* 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 without on-site OHS service.

(viii) 200 adult PCI procedures for an elective PCI service without on-site OHS service.

(b) The applicant 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 applicant hospital providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective PCI services without on-site OHS service shall participate in a data registry administered by the Department or its designee as a means to measure quality and risk adjusted outcomes within cardiac catheterization services. The Department or its designee shall require that the applicant hospital submit summary reports 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.

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

(5) Compliance with the following primary and elective PCI requirements for hospitals providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective PCI services without on-site OHS service, if applicable:

(a) The requirements set forth in Section 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 maintain a 90-minute door-to-balloon time or less in at least 75% of the primary PCI sessions (EXCLUDING PATIENTS WITH CARDIOGENIC SHOCK).

(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 PCI services by service level. The Department or its designee shall require that the applicant hospital submit all consecutive PCI cases performed within the hospital and meet data submission timeliness requirements and threshold requirements for PCI data submission, accuracy and completeness established by a data registry administered by the Department or its designee. 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. At a minimum, the applicant hospital shall report the following:

(i) the number of patients treated with and without STEMI,

(ii) the proportion of PCI patients with emergency CABG or required emergent transfer,

(iii) risk and reliability adjusted patient mortality for all PCI patients and a subset of patients with STEMI,

(iv) PCI appropriate use in elective non-acute MI cases, and

(v) rates of ad-hoc multi-vessel PCI procedures in the same session.

(e) The applicant hospital shall maintain a physician point of contact for the data registry.

(f) FOR PRIMARY PCI SERVICES WITHOUT ON-SITE OHS SERVICE AND ELECTIVE PCI SERVICES WITHOUT ON-SITE OHS SERVICE, ~~Catheterization~~ catheterization lab facility requirements and collaborative cardiologists-heart surgeon relationship requirements shall conform to all SCAI/ACC Guidelines for PCI including the SCAI/ACC/AHA Expert Consensus Document. The applicant hospital shall be liable for the cost of demonstrating compliance with these criteria.

(g) The Department shall use these thresholds and metrics in evaluating compliance: performance at a level above the 50th percentile of the statewide performance on each metric listed under subsection (d)(ii) – (v) or another level provided by the data registry designee and accepted by the Department.

(h) The Department shall notify those hospitals who fail to meet any of the minimally acceptable objective quality metric thresholds including those under subsection (d)(ii) – (v). The Department shall require these hospitals to:

(i) submit a corrective action plan within one month of notification and

(ii) demonstrate that performance has improved to meet or exceed all applicable objective quality metric thresholds, including those under subsection (d)(ii) – (v), within 12 months of notification.

(i) The applicant hospital initiating elective PCI without on-site OHS services shall have Accreditation for Cardiovascular Excellence (ACE) accreditation or an equivalent body perform an on-site review within 3, 6, and 12 months after implementation. The applicant hospital shall submit the summary reports of the on-site review to the Department AND MAINTAIN ON-GOING ACCREDITATION.

(6) Nothing in this section prohibits the Department from taking compliance action under MCL 333.22247.

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

Section 11. Methodology for computing cardiac catheterization equivalents

Sec. 11. The following shall be used in calculating procedure equivalents and evaluating utilization of a cardiac catheterization service and its laboratories:

Procedure Type	DESCRIPTION	Procedure equivalent	
		Adult	Pediatric
Diagnostic cardiac *catheterization*[A1]/peripheral session~~s~~	RIGHT HEART CATHETERIZATION, LEFT HEART CATHETERIZATION, CORONARY ANGIOGRAPHY, CORONARY ARTERY BYPASS GRAFT ANGIOGRAPHY, INTRACORONARY ADMINISTRATION OF DRUGS, FRACTIONAL FLOW RESERVE (FFR), INTRA-CORONARY IMAGING (INTRAVASCULAR ULTRASOUND (IVUS), OPTICAL COHERENCE TOMOGRAPHY (OCT)) WHEN PERFORMED WITHOUT A	1.5	2.7

Procedure Type	DESCRIPTION	Procedure equivalent	
		Adult	Pediatric
	THERAPEUTIC PROCEDURE, CARDIAC BIOPSY, INTRA-CARDIAC ECHOCARDIOGRAPHY (ICE), DIAGNOSTIC ELECTROPHYSIOLOGY STUDY, ANGIOGRAPHY IN THE PERIPHERAL ARTERIAL OR VENOUS CIRCULATION		
Therapeutic cardiac *catheterization* [A2] ~~/peripheral~~ session~~s~~	PCI, PERICARDIOCENTESIS, PACEMAKER IMPLANTATION, ICD IMPLANTATION (ENDOVASCULAR OR SUBCUTANEOUS), PACEMAKER/ICD GENERATOR CHANGE, PACEMAKER/ICD LEAD REVISION, CARDIAC ABLATION (EXCLUDING AF/VT), AND/OR STRUCTURAL HEART PROCEDURE (EXCLUDING THOSE LISTED BELOW), AND IABP, IMPELLA, ECMO, OR TANDEMHEART WHEN THIS IS THE ONLY THERAPEUTIC PROCEDURE	2.7	4.0
THERAPEUTIC PERIPHERAL SESSION	PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA), ATHERECTOMY, LASER, STENT IMPLANTATION, IVC FILTER IMPLANTATION OR RETRIEVAL, CATHETER-DIRECTED ULTRASOUND/THROMBOLYSIS, THROMBECTOMY	2.7	4.0
Complex ~~percutaneous valvular~~THERAPEUTIC session~~s~~~~*~~	PCI FOR CHRONIC TOTAL OCCLUSION (CTO), TAVR, MITRAL/PULMONARY/TRICUSPID VALVE REPAIR OR REPLACEMENT, PARAVALVULAR LEAK CLOSURE, ABLATION FOR ATRIAL FIBRILLATION (AF) OR VENTRICULAR TACHYCARDIA (VT), PACEMAKER OR ICD LEAD EXTRACTION	4.0	7.0
PROLONGED THERAPEUTIC SESSION	CARDIAC THERAPEUTIC SESSION >6 HOURS	6.0	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 OHS services.~~ PROCEDURE EQUIVALENTS FROM PERIPHERAL DIAGNOSTIC AND THERAPEUTIC PROCEDURES COUNT TOWARD THE VOLUME REQUIREMENT FOR INITIATION OF CARDIAC CATHETERIZATION SERVICES (SECTION 3) AND EXPANSION OF A CARDIAC CATHETERIZATION SERVICE (SECTION 6).			

Section 12. Documentation of projections

Sec. 12. An applicant HOSPITAL **required to project volumes shall demonstrate the following as applicable to the proposed project:**

(1) The applicant HOSPITAL 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 HOSPITAL 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.

(3) An applicant HOSPITAL proposing to initiate an elective PCI service without on-site OHS services shall demonstrate and certify that the hospital shall treat 200 or more patients with PCI annually using data during the most recent 12-month period preceding the date the application was submitted to the Department as follows:

(a) All primary PCIs performed at the applicant hospital.

(b) All inpatients transferred from the applicant hospital to another hospital for PCI.

(c) 90% of patients who received diagnostic cardiac catheterizations at the applicant hospital and received an elective PCI at another hospital within 30 days of the diagnostic catheterization (based on physician commitments).

(d) 50% of the elective PCI procedures performed by the committing physician at another hospital within 120 radius miles or 120 minutes travel time from the applicant hospital for patients who did not receive diagnostic cardiac catheterization at the applicant hospital (based on physician commitments).

(e) An applicant HOSPITAL with current OHS services and therapeutic cardiac catheterization services that is proposing to discontinue OHS services and therapeutic cardiac catheterization services and is applying to initiate primary or elective PCI services without on-site OHS services may count all primary and elective PCI at the applicant hospital within the most recent 12-month period preceding the date the application was submitted to the Department.

Section 13. Comparative reviews; Effect on prior CON Review Standards

Sec. 13. 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 ~~March 18, 2014~~JUNE 11, 2015 and effective on ~~June 2, 2014~~SEPTEMBER 14, 2015.

APPENDIX A

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

APPENDIX B

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.

Changes in the Nursing Home and HLTCU Bed Need

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Executive Summary

This report further examines and explains the 7,205 bed increase (from 39,391 to 46,596) reported in the most recent update to the Nursing Home (NH) and HLTCU Bed Need (November 15, 2017). Specifically, I examined the variables used in the the bed need methodology that influence changes in the number of beds needed: the age-specific patient day use rates (based on reported utilization data and population in the base year), the projected population in the planning year, and the adjustment factor (recently modified in the Review Standards). I report the output from three calculations of the NH–HLTCU Bed Need: 1) Base Year 2013 and Planning Year 2018 (March 8, 2016), 2) Base Year 2015 and Planning Year 2018 (August 4, 2016), and 3) Base Year 2016 and Planning Year 2020 (November 15, 2017). The first and the third calculations were made on the regular cycle of updates per the requirements of the of Review Standards and are used as the main point of comparison. The second calculation was an off-cycle request to evaluate the efforts made to improve facility reporting of patient days during this period and is included simply for reference.

To examine how changes in the three variables impacted the bed need results, I implemented a series of tests to parse the large increase in beds into its component parts based on each variable individually. While these tests could not provide an "exact" measure because all three variables changed between the first and third calculations mentioned above, the nature of the tests did allow for good approximations of the relative contributions from each variable. Specifically, 15.93% of the increase (roughly 1,148 beds) was due to changes in patient day use rates between Base Years (2013 and 2016). Some of the change in patient day use rates is very likely due to an increase in the number of patient days reported per the efforts made during this period. 50.93% of the increase (roughly 3,669 beds) was due to differences in the projected population in the Planning Years (2018 and 2020), which can be further broken down into differences by the age groups used in the methodology: 0-64 years (-4 beds), 65-74 years (684 beds), 75-84 (1,178 beds), and 85+ years (1,810). Finally, I found that 33.14% of the increase (2,388 beds) was due to the recent change of the ADC (Average Daily Census) adjustment factor used in the methodology.

While the overall increase of 7,205 beds in a single cycle may appear somewhat large, it is somewhat more easy to understand when broken down into its component parts. First, improvements in reporting between 2013 and 2016 led to generally higher patient day use rates between cycles. These higher rates were then multiplied by projected population data that forecasts growth in and a further "greying" of Michigan's population between 2018 and 2020 (which is corroborated when looking at the changes in the state's population in the recent past). The increases from the first two parts were then magnified by the change to the ADC adjustment factor, which is used as a multiplier and thus has a greater effect on planning areas with the highest projected daily bed use.

Patient day use rates by age cohort

The initial portion of the NH–HLTCU methodology found in Section 3.(1) of the Review Standards requires updating the Base Year (BY) patient day use rates for the following four age cohorts: 0-64, 65-74, 75-84, and 85+ years. The BY use rates are based on the most recently available statewide patient day utilization data and population counts. These use rates are important for the overall methodology as they provide the "expected" use of NH–HLTCU beds in the future.

To calculate the BY use rates, first, the statewide patient days for each age cohort in the BY (gathered from the CON Annual Survey data) are summed. Next, the statewide population counts in the BY (gathered from the US Census Bureau) for each age cohort are summed. The summed patient days are then divided by the summed population for each age cohort. To complete the calculation, the result is multiplied by 1,000, which produces a rate of patient days used per 1,000 people in each age cohort in the BY.

Over the previous 2+ years, this calculation was made three times. The first (March 8, 2016) used 2013 as the BY. The second (August 4, 2016) used 2015 as the BY. The third (November 15, 2017) used 2016 as the BY. The first and the third calculations were made on the regular cycle of updates to the NH–HLTCU Bed Need per the requirements of the of Review Standards. The second calculation was an off-cycle request to evaluate the efforts made to improve facility reporting of patient days in the CON Annual Survey.

The 2013, 2015, and 2016 patient days, state population, and use rates by age cohort are found in Tables 1, 2, and 3, respectively. An initial important observation from Table 1, as it relates to the increase in the most recent NH–HLTCU Bed Need, is the statewide increase of 846,640 patient days reported to the CON Annual Survey between 2013 and 2016. Notably, this represents a 6.34% increase from 2013 for the state as a whole. Given the similarity between the number of patient days reported in 2015 and 2016, the efforts to improve facility reporting appear to have been successful (and the increase suggests that patient days were heavily *under*reported in 2013). Another interesting observation from Table 1 concerns the changes in patient days reported by age cohort between 2013 and 2016, as the NH–HLTCU methodology considers these age groups separately in the calculations. Notably, the number of patient days increased for 0-64 years (490,991 or 25.04%), 65-74 years (460,998 or 23.19%), and 75-84 years (180,834 or 5.04%), but decreased for 85+ years (-205,183 or -3.34%).

Table 1. Patient Days in 2013, 2015, 2016.

Age Cohort	2013	2015	2016
0-64	1,637,392	1,941,616	2,047,383
65-74	1,987,543	2,353,618	2,448,541
75-84	3,588,437	3,761,962	3,769,271
85+	6,135,344	6,139,965	5,930,161
State	*13,348,716*	*14,197,161*	*14,195,356*

The population counts in Table 2 also provide interesting results. While the state's population grew

slightly from 2013 to 2016 (32,498 or 0.33%), the change over this period was not distributed evenly across the age cohorts. Overall, this period saw a "greying" of the state's overall population, with increases in the groups aged 65 years and up and a decrease in the less than 65 years group. Specifically, the changes were -91,664 people (-1.09%) for 0-64 years, 105,496 (12.63%) for 65-74 years, 14,011 people (3.16%) for 75-84 years, and 4,655 people (2.23%) for 85+ years.

Table 2. Population in 2013, 2015, 2016.

Age Cohort	2013	2015	2016
0-64	8,408,209	8,351,905	8,316,545
65-74	835,439	907,140	940,935
75-84	443,520	450,619	457,531
85+	208,634	212,912	213,289
State	*9,895,802*	*9,922,576*	*9,928,300*

Table 3 contains the patient day use rates calculated from the data in Tables 1 and 2. The most notable change between 2013 and 2016 is that the use rates for each of the age cohorts with people less than 85 years increased, while the use rate for the 85+ year population decreased. The reason for these changes can be easily understood when compared to the changes in patient day utilization and population in these groups from 2013 to 2016. Notably, the percent change in patient days outpaced the change in population for the 0-64 years group (25.04% vs. -1.09%), 65-74 years group (23.19% vs. 12.63%), and 75-84 years group (5.04% vs. 3.16%), which resulted in higher patient day use rates. For the 85+ years group, the decrease in patient days (-3.34%) was exacerbated by an increase in the population (2.23%), which lead to the lower use rate.

Table 3. Use Rates (patient days per 1,000 people) in 2013, 2015, 2016. The statewide rate is also included for reference, but is not used in the methodology.

Age Cohort	2013	2015	2016
0-64	195	233	247
65-74	2,380	2,595	2,603
75-84	8,091	8,349	8,239
85+	29,408	28,839	27,804
State	*1,349*	*1,431*	*1,430*

Effect of change in use rates on bed need

To estimate the effects that the change in use rates had on the most recent Bed Need calculations, I implemented the current methodology and data, but substituted the 2013 patient day use rates in lieu of the 2016 patient day use rates. This comparison enables me to answer the question, "how much of the increase in beds can be traced to the changes in the use rates between 2013 and 2016?" The result of the NH–HLTCU Bed Need using the 2013 use rates is 45,390 beds. Given the 46,596 beds calculated

using the 2016 use rates, this results in a 1,206 bed increase due to changes in the age-specific use rates.

Projected population data

The NH–HLTCU methodology requires the use of future projections of Michigan's population in the Planning Year (PY) for the NH-HLTCU Planning Areas in the specific age cohorts. The data are supplied by the State Demographer in the Department of Technology, Management & Budget. Per the methodology, the number of people in each planning area (in each age cohort) is multiplied by the age-group patient day use rates discussed above. The statewide PY population for the two years used in the calculations are provided in Table 4.

Table 4. Projected population in 2018 and 2020. Raw is the difference (in counts) between the 2018 and 2020 projections, while Pct is the percent difference between the two years.

Age Cohort	2018	2020	Raw	Pct
0-64	8,223,738	8,218,861	-4,877	-0.06%
65-74	989,396	1,080,117	90,721	9.17%
75-84	480,562	529,935	49,373	10.27%
85+	196,359	218,822	22,563	11.49%
State	*9,890,055*	*10,047,735*	*157,680*	*1.59%*

The data in Table 4 show that the projected population in Michigan was expected to increase in the higher age groups (65+ years) in these years and slightly decrease for those less than 65 years. As it pertains to the NH–HLTCU methodology, these are the age groups that utilize the most NH–HLTCU beds per capita (i.e., Table 3) and would therefore have the greatest effect on the resulting bed need calculations. The overall accuracy and trend of the population projections appear to be acceptable, given the recent population data found in Table 2.

Effect of change in projected population data on bed need

I estimated the effects of the change in the projected population year (Planning Year) on the most recent Bed Need calculations. To do this, I implemented the current methodology and data, but substituted the 2018 projected population data in place of the 2020 data. This comparison enables me to answer the question, "how much of the increase in beds can be traced to the changes in the projected population between 2018 and 2020?" The result of the NH–HLTCU Bed Need using the 2018 projected population data is 42,740 beds. Compared to the 46,596 beds calculated using the 2020 population, the result is a 3,856 bed increase due *only to* changes in the expected population. To understand this change further, I estimated the number of beds that were "needed by" each of the age cohorts from the previous calculations. The results are shown in Table 5. The table shows that roughly half (1,902) of the 3,856 bed increase is due to the expected change in the number of people in the 85+ years age group between 2018 and 2020.

Table 5. NH–HLTCU Bed Need by age group for current calculations (2020 projected population) and with 2018 projected population. Diff is the difference (in beds) between the 2018 and 2020 population projections. *Note: the age group sum of beds for 2020 and Diff is one less than the total due to rounding.*

Age Cohort	2018	2020	Diff
0-64	6,189	6,185	-4
65-74	7,848	8,567	719
75-84	12,067	13,305	1,238
85+	16,636	18,538	1,902
State	*42,740*	*46,596*	*3,856*

ADC adjustment factor

Like other bed-based health care services regulated by CON in Michigan, the NH–HLTCU bed need methodology includes a step to multiply the expected daily use of beds (Average Daily Census) in the Planning Year (in each planning area) by an "adjustment factor." This step is included to account for facilities not being able to operate at full capacity over long periods of time. In the NH–HLTCU Review Standards, this step is found in Section 3.(2)(e). The bed need in the Planning Year is calculated by dividing the Planning Year ADC by an ADC adjustment factor of 0.9 (dividing by 0.9 is equivalent to multiplying by 1.11 or 111%). This result is rounded up to the next whole number under the assumption that a partial bed is a bed.

The adjustment step in the methodology was recently changed from having two distinct ADC adjustment factors to a single factor. In the past, planning areas with an unadjusted ADC of less than 100 used 0.9, while planning areas with an unadjusted ADC of 100 or greater used 0.95 as the factor (dividing by 0.95 is equivalent to multiplying by 1.05 or 105%). A variable adjustment factor is also used in the Acute Care Hospital Standards, accounting for differing expectations of efficiency based on the size of facilities (e.g., it is more difficult to run a smaller facility near capacity). The recent change in the NH–HLTCU methodology now treats all facilities equally.

Effect of change in ADC adjustment factor on bed need

The recent change in the ADC adjustment factor has a multiplicative effect based on the ADC of the planning area. For example, if Planning Area A has an unadjusted ADC of 120, then the original approach would result in a bed need of 120 / 0.95 = 127 beds. Under the new approach, Planning Area A has a bed need of 120 / 0.9 = 134 beds. Continuing the example, if Planning Area B has an unadjusted ADC of 3,000, the original approach would result in a bed need of 3,000 / 0.95 = 3,158 beds. The new approach for Planning Area B results in a bed need of 3,334 beds. Hence, the ADC adjustment factor change would be responsible for a 7 bed increase for Planning Area A and a 176 bed increase for Planning Area B. This example simply demonstrates the multiplicative effect of the recent change.

I estimated the effect of the change in the ADC adjustment factor on the most recent Bed Need calculation. I used the former ADC adjustment steps with the current data. This comparison enables me to answer

the question, "how much of the increase in beds can be traced to the change in how ADC is adjusted in the methodology?" The result of the NH–HLTCU Bed Need using former ADC adjustment rules and factors is 44,208 beds. When compared to the 46,596 beds calculated using the single ADC adjustment factor of 0.9, this results in an increase of 2,388 beds.

Summary and Conclusions

The increase in NH–HLTCU beds reported in the previous sections tally 1,206 (use rates), 3,856 (projected population), and 2,388 beds (ADC adjustment factor). The sum of these separate calculations (7,450 beds) is slightly higher than the increase of 7,205 beds reported in the most recent cycle. This discrepancy is not a mistake, but simply because these components are integrated together (via multiplication) in the NH–HLTCU methodology and the tests performed to isolate the effects of each cannot account for the multiplicative effects. However, the contribution of the changes in the use rates and projected population data to the 7,205 bed increase can be calculated by using their relative contributions (based on a 7,450 bed increase). Using this approach, I estimate the increase in beds due only to changes in the age-specific use rates between 2013 and 2016 is 1,148 beds (15.93% of the 7,205 increase). I estimate that the increase due to a forecasted growing and greying state population between 2018 and 2020 is 3,669 beds (50.93% of the 7,205 increase). The increase due to the change in the ADC adjustment factor is 2,388 beds (33.14% of the 7,205 increase).

A statewide increase of 7,205 beds (18.3%) in only two years does appear to be quite large. Yet, this time period included two somewhat dramatic changes that would undoubtably result in increases in the number of NH-HLTCU beds needed as calculated by the methodology. First, there were efforts to increase and improve facility reporting of patient utilization data between 2013 and 2016, which largely increased the use rates (that were likely artificially low due to underreporting in the prior update). Second, by changing the methodology to only include a single ADC adjustment factor of 0.9, the *only* effect could be an increase in the bed need (holding other factors equal). The most surprising finding was that roughly half of the increase in the bed need was due to differences in the projected population between 2018 and 2020; however, the forecast of a slightly larger and older state population in this time period is in line with recent past trends in Michigan and appears to be reasonable.

MICHIGAN DEPARTMENT OF ~~COMMUNITY~~ HEALTH AND HUMAN SERVICES

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 AND HUMAN SERVICES (MD~~C~~HHS).

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

(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.

(h) "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.

(i) "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.

(j) “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.

(k) "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.

(l) "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).

(m) "Planning area" means the groups of counties shown in Section ~~10~~11.

(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~~9.

(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~~10.

SECTION 4. REQUIREMENTS TO REPLACE AN EXISTING OHS SERVICE

SEC. 4. REPLACE AN EXISTING ADULT OR PEDIATRIC OHS SERVICE MEANS RELOCATING AN EXISTING ADULT OR PEDIATRIC OHS SERVICE TO A NEW GEOGRAPHIC LOCATION OF AN EXISTING LICENSED HOSPITAL. THE TERM DOES NOT INCLUDE THE REPLACEMENT OF AN EXISTING OHS SERVICE AT THE SAME SITE. AN APPLICANT REQUESTING TO REPLACE AN EXISTING OHS SERVICE SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.

(1) AN APPLICANT PROPOSING TO REPLACE AN EXISTING OHS SERVICE SHALL DEMONSTRATE THE FOLLOWING:

(a) THE EXISTING OHS SERVICE TO BE REPLACED HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(b) THE PROPOSED NEW SITE IS A HOSPITAL THAT IS OWNED BY, IS UNDER COMMON CONTROL OF, OR HAS A COMMON PARENT AS THE APPLICANT HOSPITAL.

(c) THE APPLICANT IS SIMULTANEOUSLY REPLACING ITS OHS SERVICE AND ITS CARDIAC CATHETERIZATION SERVICE TO THE PROPOSED NEW SITE.

(d) THE PROPOSED NEW SITE IS WITHIN THE SAME PLANNING AREA OF THE SITE AT WHICH AN EXISTING OHS SERVICE IS LOCATED.

(e) THE EXISTING OHS SERVICE TO BE RELOCATED PERFORMED AT LEAST THE APPLICABLE MINIMUM NUMBER OF OPEN HEART SURGICAL CASES SET FORTH IN SECTION 8 AS OF THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT UNLESS THE OHS SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF AN ENTIRE HOSPITAL TO A NEW GEOGRAPHIC SITE.

(f) THE CARDIAC CATHETERIZATION AND OHS SERVICES SHALL CEASE OPERATION AT THE ORIGINAL SITE PRIOR TO BEGINNING OPERATION AT THE NEW SITE.

Section 45. Requirements to acquire an existing open heart surgery service

Sec. 45. 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~~ 8 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~~ 8 of these standards.

Section ~~5~~6. Requirements for Medicaid participation

Sec. ~~5~~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 ~~6~~7. Requirements for MIDB data commitments

Sec. ~~6~~7. 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~~8. Project delivery requirements and terms of approval for all applicants

Sec. ~~7~~8. 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~~9. Methodology for computing the number of adult open heart surgical cases

Sec. ~~8~~9. (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~~9(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~~9(1)(a)(ii) will be divided by the number of discharges identified in subsection ~~8~~9(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~~9(1)(b)(ii) will be divided by the number of discharges identified in subsection ~~8~~9(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~~9(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~~10. Methodology for computing the number of pediatric open heart surgical cases

Sec. ~~9~~10. (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~~10(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~~10(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~~10(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~~10(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~~10(1)(f) will be divided by the number of discharges identified in subsection ~~9~~10(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~~11. Planning Areas

Sec. ~~10~~11. 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~~12. Effect on prior planning policies; comparative reviews

Sec. ~~11~~12. (1) These CON Review Standards supersede and replace the CON Review Standards for OHS Services approved by the CON Commission on ~~September 17, 2013~~MARCH 18, 2014 and effective on ~~November 15, 2013~~JUNE 2, 2014.

(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	.622129
B	441.01, 441.03 441.1, 441.2 441.6, 441.7	Aortic Aneurysm	.678981
C	745 – 747.99	Congenital Anomalies	.467532
D	414 – 414.99	Other Chronic Ischemic	.294728
E	410 – 410.99	Acute Myocardial Infarct	.089600
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	.012813

NON-PRINCIPAL DIAGNOSES

GROUP	MAJOR ICD-9-CM CODE GROUP	CATEGORY	ADULT OPEN HEART UTILIZATION WEIGHTS
A	745 – 747.99	Congenital Anomalies	.017280
B	441.01, 441.03 441.1, 441.2 441.6, 441.7	Aortic Aneurysm	.028159
C	410 – 410.99	Acute Myocardial Infarct	.012194
D	394 – 397.9 421 – 421.9 424 – 424.99	Valves	.007711
E	414 – 414.99	Other Chronic Ischemic	.001633

APPENDIX A continued

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	.001222

Source: Calculated based on the 2014 Michigan Inpatient Data Base
Amended and Effective September 1, 2016

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	.179681
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	.013025

Source: Calculated based on the 2014 Michigan Inpatient Data Base
Amended and Effective September 1, 2016

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
		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

APPENDIX D continued

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
411 – 411.99 Continued	All Other Heart Conditions Continued	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
		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

APPENDIX D continued

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
901 – 901.9 Continued	All Other Heart Conditions Continued	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
		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

APPENDIX D continued

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
901 – 901.9 Continued	All Other Heart Conditions Continued	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
		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

APPENDIX D continued

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
901 – 901.9 Continued	All Other Heart Conditions Continued	S25.501A	Unspecified Injury of Intercostal Blood Vessels, Right Side, Initial Encounter
		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
		S25.891A	Other Specified Injury of Other Blood Vessels of Thorax, Right Side, Initial Encounter

APPENDIX D continued

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
901 – 901.9 Continued	All Other Heart Conditions Continued	S25.892A	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

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"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
		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

APPENDIX E continued

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
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
		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

APPENDIX E continued

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
901.0 – 901.9 Continued	All Other Heart Conditions Continued	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
		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

APPENDIX E continued

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
901.0 – 901.9 Continued	All Other Heart Conditions Continued	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
		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

APPENDIX E continued

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
901.0 – 901.9 Continued	All Other Heart Conditions Continued	S25.501A	Unspecified Injury of Intercostal Blood Vessels, Right Side, Initial Encounter
		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
		S25.891A	Other Specified Injury of Other Blood Vessels of Thorax, 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	S25.892A	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

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"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.

HOSPITAL BEDS STANDARD ADVISORY COMMITTEE
Report to the Certificate of Need Commission

March 27, 2018

Mr. Chairman,

The Hospital Bed Standard Advisory Committee (HBSAC) was approved by the Commission on March 16, 2017. The charges delegated to the HBSAC were as follows:

The Hospital Bed SAC should review and recommend any necessary changes to the Hospital Bed Standards with consideration of the following:

1. Review and update or eliminate, if necessary, the language in section 6(4)(f), which states, "*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.*"
2. Review and update, if necessary, the language throughout section 12, titled "Additional requirements for applications included in comparative reviews".
3. Review and update, if necessary, the space lease and lease renewal at hospitals.
4. Review the concept of replacing and relocating inpatient rehabilitation beds and update the standard, if necessary.
5. Consider any necessary technical or other changes e.g., updates or modifications consistent with other CON review standards and the Public Health Code.

The HBSAC met 6 times to consider and respond to the charges. It was agreed that the work of the committee would be more efficient if sub-committees were formed to identify and address issues, and to make recommendations in response to charges 2 and 4. The remaining charges were considered independently during each meeting.

The committee's report to the Commission for each charge is as follows:

Charge #1: "Review and update or eliminate, if necessary, the language in Section 6(4)(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"). The committee agreed to propose to eliminate the language in Section 6(4)(f). Rationale: After some discussion, the committee determined that good faith efforts to relocate acute care beds from other licensed acute care hospitals requires the use of time and resources that do not result in action. Acute care beds are not being relocated from one facility to another.

Charge #2: Review and update, if necessary, the language throughout section 12, titled "Additional requirements for applications included in comparative reviews." The HBSAC formed a subcommittee to review and address section 12, and to recommend updates to the language. The subcommittee recommended modifying the scoring for comparative review. The current scoring system is based on percentile rankings. The subcommittee recommended the addition of quality measures (20 points) and proposed a point system for comparative review that also includes: uninsured days (10 points), Medicaid days (20 points), cost per bed (15 points), market share (10 points) and geographic access to care (10 points). The HBSAC accepted the subcommittee's recommendation with discussion and voted to submit the proposed requirements for comparative review to the Commission. Rationale: The committee agreed that quality measures should be included in comparative review. While reviewing the requirements for comparative review, the committee also determined that since adding quality requirements would require adjustment in scoring, language is proposed to clarify the scoring for additional categories by converting comparative percentages to points. For example, an applicant with the highest market share shall be awarded 10 points.

Charge #3: Review and update, if necessary, the space lease and lease renewal at hospitals. The committee reviewed and made proposed updates to the space lease and lease renewal by clarifying that requirements for approval apply to those situations where an applicant is proposing to acquire an existing hospital or renewal of an existing hospital lease. In

addition, the proposed language change makes exceptions in certain cases (if the lease renewal will not result in a change in bed capacity and the licensed site does not change as a result of the lease renewal), and for certain types of facilities (LTAC hospital, IRF hospital or alcohol and substance facility within an existing licensed host hospital). Rationale: the hospital bed language referring to lease renewal is now consistent with language in nursing home and other sections of CON.

Charge #4: Review the concept of replacing and relocating inpatient rehabilitation beds and update the standard, if necessary. The HBSAC formed a subcommittee to review and address the charge to the committee. The resulting recommendations include criteria for defining and relocating inpatient rehabilitation facility (IRF) beds within a specified replacement zone, as well as to a new licensed IRF hospital site. If the application involves the development of a new licensed IRF hospital site, the applicant must meet all of the following criteria:

- The applicant has demonstrated, at the time of the CON filing, it is operating under high occupancy standards.
- The applicant has demonstrated, at the time of CON filing, that the beds to be replaced are IRF beds that meet the Title XVIII requirements of the Social Security Act for exemption from PPS (Medicare) as an IRF hospital.
- The new IRF hospital will have at least 40 IRF beds if located in a county with a population of 200,000 or more; or at least 25 IRF beds if located in a county with a population of less than 200,000.
- As part of the phasing of the replacement of IRF beds to the new site, the applicant may retain, for 36 months from the time of activation of the new site, up to eight IRF beds at the existing hospital site; any IRF beds at the existing site that have not been transitioned to the new site within the 36 month time period shall not be utilized for inpatient rehabilitation and shall revert back to acute medical surgical hospital beds.

Following review and discussion, the HBSAC voted to submit the proposed language changes to the Commission for adoption.

Rationale: There is a growing patient demand for Inpatient Rehabilitation care. Since the CON standards do not recognize the different and separable levels of acute care or the non-contiguous replacement of IRF

beds, should there be a need for additional IRF beds but no available space, there is no way to expand an existing IRF unit within a hospital, or to relocate the beds. To allow for replacement of IRF beds, language changes are proposed in definitions, requirements for approval to replace beds and project delivery requirements. These proposed changes followed specific principles: any amendment does not compromise the overall integrity of the Hospital Bed Standards; geographic separation of IRF beds would be applicable only to those organizations approved by Medicare to participate as an exempt Inpatient Rehabilitation Hospital; CON standards for Hospital Beds will follow the distinct levels of care per regulatory definition; and the result will provide accessible, high quality, acute rehabilitation care in an appropriate setting.

Charge #5: Consider any necessary technical or other changes e.g., updates or modifications consistent with other CON review standards and the Public Health Code. The Department recommended several technical changes, which the committee accepted and are presenting for adoption. Rationale: The Department provided changes that ensure that the language in the standards are accurate and updated.

Respectfully Submitted,

Renee Turner-Bailey, M.H.S.A.
Chairperson, Hospital Bed Standard Advisory Committee

Report of the Hospital Beds Standard Advisory Committee

Certificate of Need Commission Meeting
March 27, 2018

Renee Turner-Bailey, M.H.S.A.
Chairperson

Hospital Beds Standard Advisory Committee (HBSAC)

- The HBSAC met 6 times to address the charges from the Certificate of Need (CON) Commission
- The HBSAC agreed in the early meetings to form subcommittees to address charges 2 and 4.
- The subcommittees met to consider all issues related to the charges, made presentations to the HBSAC and made informed recommendations to address the charges

Recommendations of the HBSAC by Charge

Charge #1: Review and update or eliminate, if necessary, the language in section 6(4)(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.)

The HBSAC agreed to recommend elimination of the language in Section 6(4)(f).

Recommendations of the HBSAC by Charge

Charge #2: Review and update, if necessary, the language throughout section 12, titled "Additional requirements for applications included in comparative reviews."

The committee is proposing updates to the requirements for comparative review as follows:

- **Quality measures (CMS star ratings) : 20 points maximum**
- **Uninsured days: 10 points maximum**
- **Medicaid days: 20 points maximum**
- **Cost per bed: 15 points maximum**
- **Market share: 10 points maximum**
- **Comparative Review: 10 points maximum**

Recommendations of the HBSAC by Charge

Charge #3: Review and update, if necessary, the space lease and lease renewal at hospitals.

The committee proposed the following updates to the space lease and lease renewal at hospitals:

- **Clarify that requirements for approval apply to those situations where an applicant is proposing to acquire an existing hospital or renewal of an existing hospital lease**
- **Space lease and lease renewal language changes do not apply if the lease renewal will not result in a change in bed capacity and the licensed site does not change as a result of the lease renewal**
- **Certain types of facilities are excluded: LTAC hospital, IRF hospital or alcohol and substance facility within an existing licensed host hospital**

Recommendations of the HBSAC by Charge

Charge #4: Review the concept of replacing and relocating inpatient rehabilitation beds and update the standard, if necessary.

The committee recommended the criteria for defining and relocating inpatient rehabilitation facility (IRF) beds within a specified replacement zone, as well as to a new licensed IRF hospital site:

"IRF bed" means a licensed bed within an IRF hospital or unit that has been approved to participate in the Medicare program as a prospective payment system exempt inpatient rehabilitation hospital

Recommendations of the HBSAC by Charge

Charge #4: Review the concept of replacing and relocating inpatient rehabilitation beds and update the standard, if necessary.

The committee recommended the criteria for defining and relocating inpatient rehabilitation facility (IRF) beds within a specified replacement zone, as well as to a new licensed IRF hospital site:

"Replace IRF beds" means a change in the location of all IRF beds from an existing site to a site within the replacement zone for IRF beds

Recommendations of the HBSAC by Charge

Charge #4: Review the concept of replacing and relocating inpatient rehabilitation beds and update the standard, if necessary.

The committee developed criteria for developing a new licensed IRF hospital site:

An applicant has demonstrated, at the time of the CON filing, it is operating under high occupancy

Recommendations of the HBSAC by Charge

Charge #4: Review the concept of replacing and relocating inpatient rehabilitation beds and update the standard, if necessary.

The committee developed criteria for developing a new licensed IRF hospital site:

An applicant has demonstrated that the beds to be replaced are IRF beds that meet the Title XVIII requirements of the Social Security Act (Medicare beds)

Recommendations of the HBSAC by Charge

Charge #4: Review the concept of replacing and relocating inpatient rehabilitation beds and update the standard, if necessary.

The committee developed criteria for developing a new licensed IRF hospital site:

An applicant proposing to replace IRF beds in a hospital within the IRF replacement zone shall demonstrate the proposed project will result in an IRF hospital of at least 40 IRF beds if located in a county with a population of 200,000 or more, or 25 IRF beds if located in a county with a population of less than 200,000.

Recommendations of the HBSAC by Charge

Charge #4: Review the concept of replacing and relocating inpatient rehabilitation beds and update the standard, if necessary.

The committee developed criteria for allowing for phasing of the replacement of IRF beds to the new site:

An applicant may retain, for 36 months from the time of activation of the new site, up to 8 IRF beds at the existing hospital site. Any beds not transitioned shall revert to acute medical-surgical beds.

Recommendations of the HBSAC by Charge

Charge #4: Review the concept of replacing and relocating inpatient rehabilitation beds and update the standard, if necessary.

The committee clarified that the new IRF hospital will maintain a connection to the host hospital:

- **The existing hospital site shall delicense the same number of IRF beds proposed by the applicant**
- **The new IRF hospital shall not be subject to comparative review**
- **The new IRF hospital shall be assigned to the same hospital group as the hospital where the IRF beds originated**

Recommendations of the HBSAC by Charge

Charge #4: Review the concept of replacing and relocating inpatient rehabilitation beds and update the standard, if necessary.

If the new IRF hospital ceases operations as an IRF hospital, the beds must be disposed of by one of the following means:

- **Relocate the replaced IRF beds back to the site of origin**
- **Relocate any IRF beds approved under high occupancy to the site of origin if they are to be utilized as an IRF bed; OR**
- **Delicense any IRF beds approved under high occupancy if they are not to be utilized as an IRF bed**

Recommendations of the HBSAC by Charge

Charge #5: Consider any necessary technical or other changes e.g., updates or modifications consistent with other CON review standards of the Public Health Code.

The department made technical recommendations to the language which the HBSAC accepted and voted to propose for approval.

MICHIGAN DEPARTMENT OF ~~COMMUNITY~~ HEALTH AND HUMAN SERVICES

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.

(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 AND HUMAN SERVICES (MD~~C~~HHS).

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

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

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

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

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

(iii) LTAC and Inpatient Rehabilitation Facility (IRF) 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 (LARA) 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, IRF hospital, or alcohol and substance abuse hospital, to begin operation.

(v) "INPATIENT REHABILITATION FACILITY BED" OR "IRF BED" MEANS A LICENSED HOSPITAL BED WITHIN AN IRF HOSPITAL OR UNIT THAT HAS BEEN APPROVED TO PARTICIPATE IN THE TITLE XVIII (MEDICARE) PROGRAM AS A PROSPECTIVE PAYMENT SYSTEM (PPS) EXEMPT INPATIENT REHABILITATION HOSPITAL IN ACCORDANCE WITH 42 CFR PART 412 SUBPART P.

(~~v~~w) "Inpatient Rehabilitation Facility hospital" or "IRF hospital" means a hospital that has been approved to participate in the Title XVIII (Medicare) program as a prospective payment system (PPS) exempt Inpatient Rehabilitation Hospital in accordance with 42 CFR Part 412 Subpart P.

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

(~~x~~y) "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.

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

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

(~~aa~~bb) "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.

(~~bb~~cc) "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.

(~~cc~~dd) "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.

(~~dd~~ee) "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.

(~~ee~~ff) "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).

(~~ff~~gg) "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.

(~~gg~~hh) "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.

(~~hh~~ii) "Planning year" means five years beyond the base year for which hospital bed need is developed.

(~~ii~~jj) "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.

(~~jj~~kk) "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.

(~~kk~~ll) "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.

(~~ll~~mm) "RENEWAL OF LEASE" MEANS EXECUTION OF A LEASE BETWEEN THE LICENSEE AND A REAL PROPERTY OWNER IN WHICH THE TOTAL LEASE COSTS EXCEED THE CAPITAL EXPENDITURE THRESHOLD.

(nn) "Replace beds" means a change in the location of the licensed hospital, the replacement of a portion of the licensed beds at the same licensed site, or the one-time replacement of less than 50% of the licensed beds to a new site within 250 yards of the building on the licensed site containing more than 50% of the licensed beds, which may include a new site across a highway(s) or street(s) as defined in MCL 257.20 and excludes a new site across a limited access highway as defined in MCL 257.26. 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.

(oo) "REPLACE IRF BEDS" MEANS A CHANGE IN THE LOCATION OF ALL IRF BEDS FROM AN EXISTING SITE TO A NEW SITE WITHIN THE REPLACEMENT ZONE FOR IRF BEDS.

(~~mm~~pp)"Replacement zone" means a proposed licensed site that is (i) in the same hospital group as the existing licensed site as determined by the Department in accord with Section 3 of these standards and (ii) on the same site, on a contiguous site, or on a site within 2 miles (5 MILES FOR IRF BEDS) of the existing licensed site if the existing licensed site is located in a county with a population of 200,000 or more, or on a site within 5 miles (10 MILES FOR IRF BEDS) of the existing licensed site if the existing licensed site is located in a county with a population of less than 200,000.

(~~nn~~qq) "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.

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

(~~pp~~ss) "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 I. 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 ≤ 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 effective date of the bed-need numbers shall be established by the Commission.

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

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

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

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

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

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

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

(2) An applicant proposing to begin operation as a new LTAC hospital, IRF hospital or alcohol and substance abuse hospital within an existing licensed, host hospital shall demonstrate that it meets all of the requirements of this subsection:

(a) If the LTAC or IRF hospital applicant described in this subsection does not meet the Title XVIII requirements of the Social Security Act for exemption from PPS as an LTAC or IRF hospital within 12 months after beginning operation, then it may apply for a six-month extension in accordance with R325.9403 of the CON rules. If the applicant fails to meet the Title XVIII requirements for PPS exemption as an LTAC or IRF hospital within the 12 or 18-month period, then the CON granted pursuant to this section shall expire automatically.

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

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

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

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

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

(B) Delicensure of the hospital beds; or

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

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

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

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

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

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

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

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

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

(i) In the hospital group pursuant to Section 8(2)(a), or

(ii) in the HSA pursuant to Section 8(2)(b).

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

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

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

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

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

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

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

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

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

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

(a) The beds are being added at the existing licensed hospital site, OR ARE BEING REPLACED TO A NEW IRF HOSPITAL SITE BEING CREATED UNDER SECTION 7(6) AS PART OF THE SAME CON APPLICATION.

(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 transp~~lan~~t 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, TO REPLACE ALL LICENSED IRF BEDS TO A NEW SITE, to replace a portion of the licensed beds at the existing licensed site, or the one-time replacement of less than 50% of the licensed beds to a new site within 250 yards of the building on the licensed site containing more than 50% of the licensed beds, which may include a new site across a highway(s) or street(s) as defined in MCL 257.20 and excludes a new site across a limited access highway as defined in MCL 257.26.

(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.

(6) IF THE APPLICATION INVOLVES THE DEVELOPMENT OF A NEW LICENSED IRF HOSPITAL SITE, AN APPLICANT PROPOSING TO REPLACE IRF BEDS WITHIN THE REPLACEMENT ZONE SHALL DEMONSTRATE THAT IT MEETS ALL OF THE REQUIREMENTS OF THIS SUBSECTION:
(a) THE NEW LICENSE CREATED BY THE PROPOSED PROJECT SHALL ONLY BE UTILIZED FOR INPATIENT REHABILITATION BEDS.
(b) THE APPLICANT HOSPITAL HAS DEMONSTRATED, AT THE TIME OF THE CON FILING, IT IS OPERATING UNDER HIGH OCCUPANCY AS GOVERNED BY SECTION 6(4) OF THESE STANDARDS.
(c) THE APPLICANT HAS DEMONSTRATED, AT THE TIME OF CON FILING, THAT THE BEDS TO BE REPLACED ARE EITHER IRF BEDS THAT MEET THE TITLE XVIII REQUIREMENTS OF THE SOCIAL SECURITY ACT FOR EXEMPTION FROM PPS AS AN IRF HOSPITAL, OR HIGH OCCUPANCY BEDS BEING REQUESTED UNDER SECTION 6(4) AS PART OF THE SAME CON APPLICATION.
(d) THE NEW IRF HOSPITAL WILL HAVE AT LEAST 40 IRF BEDS IF LOCATED IN A COUNTY WITH A POPULATION OF 200,000 OR MORE; OR AT LEAST 25 IRF BEDS IF LOCATED IN A COUNTY WITH A POPULATION OF LESS THAN 200,000.
(e) AS PART OF THE PHASING OF THE REPLACEMENT OF IRF BEDS TO THE NEW SITE, THE APPLICANT MAY RETAIN, FOR 36-MONTHS FROM THE TIME OF ACTIVATION OF THE NEW SITE, UP TO EIGHT IRF BEDS AT THE EXISTING HOSPITAL SITE. ANY IRF BEDS AT THE EXISTING SITE THAT HAVE NOT BEEN TRANSITIONED TO THE NEW SITE WITHIN THE 36-MONTH TIME PERIOD SHALL NOT BE UTILIZED FOR INPATIENT REHABILITATION AND SHALL REVERT BACK TO ACUTE MEDICAL-SURGICAL HOSPITAL BEDS.

(f) THE PROPOSED PROJECT TO BEGIN OPERATION OF A NEW SITE, UNDER THIS SUBSECTION, SHALL CONSTITUTE A CHANGE IN BED CAPACITY UNDER SECTION 1(2) OF THESE STANDARDS.
(g) THE EXISTING HOSPITAL SITE SHALL DELICENSE THE SAME NUMBER OF IRF BEDS PROPOSED BY THE APPLICANT FOR LICENSURE IN THE NEW IRF HOSPITAL.
(h) APPLICANTS PROPOSING A NEW IRF HOSPITAL UNDER THIS SUBSECTION SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW.
(i) THE NEW IRF HOSPITAL SHALL BE ASSIGNED TO THE SAME HOSPITAL GROUP AS THE HOSPITAL WHERE THE IRF BEDS ORIGINATED.
(j) IF THE IRF HOSPITAL APPROVED UNDER THIS SUBSECTION CEASES OPERATION AS AN IRF HOSPITAL, THE BEDS LICENSED AS PART OF THE NEW IRF HOSPITAL MUST BE DISPOSED OF BY ONE OF THE FOLLOWING MEANS:
(i) RELOCATE THE REPLACED IRF BEDS BACK TO THE SITE OF ORIGIN;
(ii) RELOCATE ALL IRF BEDS APPROVED UNDER HIGH OCCUPANCY TO THE SITE OF ORIGIN IN SUBSECTION (i) IF THEY ARE TO BE UTILIZED AS AN IRF BED; OR
(iii) DELICENSE ANY IRF BEDS APPROVED UNDER HIGH OCCUPANCY IF THEY ARE NOT TO BE UTILIZED AS AN IRF BED.

Section 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) AN APPLICANT APPROVED FOR THE REPLACEMENT OF IRF BEDS UNDER SECTION 7(6) TO A NEW NON-CONTIGUOUS SITE SHALL BE IN COMPLIANCE WITH THE FOLLOWING:
(a) THE REPLACED IRF BEDS SHALL MAINTAIN THEIR PPS EXEMPT INPATIENT REHABILITATION HOSPITAL STATUS.
(b) THE NEW LICENSE CREATED BY THE PROPOSED PROJECT WILL ONLY BE UTILIZED FOR INPATIENT REHABILITATION BEDS.

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

Section 10. Department inventory of beds

Sec. 10. The Department shall maintain and provide on request a listing of the Department inventory of beds for each hospital group.

Section 11. Effect on prior planning policies; comparative reviews

Sec. 11. (1) These CON review standards supersede and replace the CON standards for hospital beds approved by the CON Commission on ~~March 18, 2014~~DECEMBER 11, 2014 and effective ~~June 2, 2014~~MARCH 20, 2015.

(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 12. Additional requirements for applications included in comparative reviews

Sec. 12. (1) ~~Except for those applications for limited access areas, a~~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 SAME TYPE OF applications (LIMITED ACCESS AREA OR NON-LIMITED ACCESS AREA) ~~-~~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 APPLICANT'S CMS STAR RATINGS VIA HOSPITAL COMPARE AS OF THE DATE OF APPLICATION AS FOLLOWS:

A QUALIFYING PROJECT WILL BE AWARDED POINTS BASED ON THE APPLICANT'S QUALITY OF CARE AS MEASURED BY THE OVERALL STAR RATINGS AVAILABLE THROUGH CMS' HOSPITAL COMPARE. FOR PURPOSES OF EVALUATING THIS CRITERION, AN AVERAGE SHALL BE CALCULATED BASED ON THE OVERALL STAR RATINGS OF THE APPLICANT AND 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. APPLICANTS SHALL BE RANKED IN ORDER ACCORDING TO THIS CALCULATED OVERALL STAR RATING AVERAGE.

STAR RATING	POINTS AWARDED
APPLICANT WITH HIGHEST AVERAGE STAR RATING	20 POINTS
ALL OTHER APPLICANTS	APPLICANT'S AVERAGE STAR RATING DIVIDED BY THE HIGHEST APPLICANT'S STAR RATING, THEN MULTIPLIED BY 15

EXAMPLE: THE HIGHEST APPLICANT HAS AN AVERAGE STAR RATING OF 3.4	20 POINTS
APPLICANT WITH STAR RATING OF 3.1	(3.1 ÷ 3.4) X 15 = 13.7 is 14 POINTS
APPLICANT WITH STAR RATING OF 3.0	(3.0 ÷ 3.4) X 15 = 13.2 is 13 POINTS

FOR PURPOSES OF EVALUATING THIS CRITERION, APPLICANTS SHALL SUBMIT THE OVERALL CMS STAR RATING AVAILABLE AT THE TIME OF THE SUBMISSION OF THE CON APPLICATION FOR THE APPLICANT AND EACH CURRENTLY LICENSED HOSPITAL UNDER COMMON OWNERSHIP OR CONTROL LOCATED IN THE SAME HEALTH SERVICE AREA AS THE PROPOSED HOSPITAL BEDS. 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. STAR RATINGS SHALL BE ROUNDED TO THE NEAREST 1/10, AND POINTS AWARDED SHALL BE ROUNDED TO THE NEAREST WHOLE NUMBER, I.E. NUMBERS ENDING IN .5 OR HIGHER, ROUND UP, AND NUMBERS ENDING IN .4 OR LOWER, ROUND DOWN.

(b) 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~~ UNINSURED DAYS AS MEASURED AS A PERCENTAGE OF TOTAL DAYS as set forth in the following table. The applicant's ~~uncompensated care volume~~ UNINSURED PERCENTAGE will be the cumulative of all UNINSURED INPATIENT MED/SURG AND UNINSURED INPATIENT REHAB DAYS DIVIDED BY THE CUMULATIVE OF ALL INPATIENT MED/SURG AND INPATIENT REHAB DAYS AT 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. FOR PURPOSES OF EVALUATING THIS CRITERION, AN APPLICANT SHALL SUBMIT THE MOST RECENT REVIEWED AND ACCEPTED MEDICAID COST REPORT FOR EACH CURRENTLY LICENSED HOSPITAL UNDER COMMON OWNERSHIP OR CONTROL WITHIN THE SAME HEALTH SERVICE AREA. If a hospital under common ownership or control with the applicant has not filed a MEDICAID 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~~

UNINSURED DAYS	POINTS AWARDED
APPLICANT WITH HIGHEST PERCENT OF UNINSURED DAYS	10 POINTS
ALL OTHER APPLICANTS	APPLICANT'S PERCENT OF UNINSURED DAYS DIVIDED BY THE HIGHEST APPLICANT'S PERCENT OF UNISURED DAYS, THEN MULTIPLIED BY 7
EXAMPLE: THE HIGHEST APPLICANT HAS 5.3% UNINSURED DAYS	10 POINTS
APPLICANT WITH 5.0% DAYS	(5.0 ÷ 5.3) X 7 = 6.6 is 7 POINTS
APPLICANT WITH 3.0% DAYS	(3.0 ÷ 5.3) X 7 = 4.0 is 4 POINTS

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. PERCENTAGES OF DAYS SHALL BE ROUNDED TO THE NEAREST 1/10 (E.G. 5.3%), AND POINTS AWARDED SHALL BE ROUNDED TO THE NEAREST

WHOLE NUMBER, I.E. NUMBERS ENDING IN .5 OR HIGHER, ROUND UP, AND NUMBERS ENDING IN .4 OR LOWER, ROUND DOWN.

(~~bc~~) A qualifying project will be awarded points based on the ~~health service area percentile~~ rankING of the applicant's Medicaid ~~volume as measured by percentage of gross hospital revenues~~ DAYS AS MEASURED AS A PERCENTAGE OF TOTAL DAYS as set forth in the following table. For purposes of scoring, the applicant's Medicaid ~~volume~~ PERCENTAGE will be the cumulative of all TITLE XIX AND HEALTHY MICHIGAN INPATIENT MED/SURG AND INPATIENT REHAB DAYS DIVIDED BY THE CUMULATIVE OF ALL INPATIENT MED/SURG AND INPATIENT REHAB DAYS AT 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. FOR PURPOSES OF EVALUATING THIS CRITERION, AN APPLICANT SHALL SUBMIT THE MOST RECENT REVIEWED AND ACCEPTED MEDICAID COST REPORT FOR EACH CURRENTLY LICENSED HOSPITAL UNDER COMMON OWNERSHIP OR CONTROL WITHIN THE SAME HEALTH SERVICE AREA. If a hospital under common ownership or control with the applicant has not filed a MEDICAID 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~~

MEDICAID DAYS	POINTS AWARDED
APPLICANT WITH HIGHEST PERCENT OF MEDICAID DAYS	20 POINTS
ALL OTHER APPLICANTS	APPLICANT'S PERCENT OF MEDICAID DAYS DIVIDED BY THE HIGHEST APPLICANT'S PERCENT OF MEDICAID DAYS, THEN MULTIPLIED BY 15
EXAMPLE: THE HIGHEST APPLICANT HAS 15.3% MEDICAID DAYS	20 POINTS
APPLICANT WITH 15.0% DAYS	(15.0 ÷ 15.3) X 15 = 14.7 is 15 POINTS
APPLICANT WITH 12.2% DAYS	(12.2 ÷ 15.3) X 15 = 12.0 is 12 POINTS

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. PERCENTAGES OF DAYS SHALL BE ROUNDED TO THE NEAREST 1/10 (E.G. 5.3%), AND POINTS AWARDED SHALL BE ROUNDED TO THE NEAREST WHOLE NUMBER, I.E. NUMBERS ENDING IN .5 OR HIGHER, ROUND UP, AND NUMBERS ENDING IN .4 OR LOWER, ROUND DOWN.

(~~cd~~) 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~~ 15 pts
Closure of hospital(s)
which creates a bed need ~~-1~~5 pts

(e) A QUALIFYING PROJECT WILL BE AWARDED POINTS BASED ON THE APPLICANT'S TOTAL PROJECT COSTS PER HOSPITAL BED. FOR PURPOSES OF THIS CRITERION, TOTAL PROJECT COSTS SHALL BE DEFINED AS THE TOTAL COSTS FOR CONSTRUCTION AND RENOVATION, SITE WORK, ARCHITECTURAL/ ENGINEERING AND CONSULTING FEES, CONTINGENCIES, FIXED EQUIPMENT, CONSTRUCTION MANAGEMENT AND PERMITS. THE PROPOSED PROJECT MUST INCLUDE SPACE FOR INPATIENT CARE, AND, IF NOT ALREADY AVAILABLE AT THE PROPOSED SITE, SPACE TO PROVIDE 24 HOUR/7 DAYS A WEEK SURGICAL, EMERGENCY AND IMAGING SERVICES. POINTS SHALL BE AWARDED IN ACCORDANCE WITH THE TABLE BELOW:

COST PER BED	POINTS AWARDED
APPLICANT WITH LOWEST COST PER BED	15 POINTS
ALL OTHER APPLICANTS	THE LOWEST COST PER BED IN THE COMPARE GROUP DIVIDED BY THE APPLICANT'S COST PER BED, THEN MULTIPLIED BY 10
EXAMPLE: THE LOWEST COST APPLICANT HAS $698,000 PER BED	15 POINTS
APPPLICANT WITH $710,000	($698,000 ÷ 710,000) X 10 = 9.8 is 10 POINTS
APPPLICANT WITH $975,000 PER BED	($698,000 ÷ 975,000) X 10 = 7.2 is 7 POINTS

POINTS SHALL NOT BE AWARDED UNDER THIS SECTION FOR ANY PROJECT THAT PROPOSES TO ADD BEDS AT A LEASED FACILITY. COSTS SHALL BE ROUNDED TO THE NEAREST WHOLE DOLLAR, AND POINTS AWARDED SHALL BE ROUNDED TO THE NEAREST WHOLE NUMBER. , I.E. NUMBERS ENDING IN .5 OR HIGHER, ROUND UP, AND NUMBERS ENDING IN .4 OR LOWER, ROUND DOWN.

(~~d~~f) A qualifying project will be awarded points based on the percentage of the applicant's historical market share of inpatient ~~***discharges***~~ ***DAYS*** 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~~ OF THE MARKET AREA'S PATIENT DAYS SERVED BY THE APPLICANT AND ALL CURRENTLY LICENSED MICHIGAN HOSPITALS UNDER COMMON OWNERSHIP AND CONTROL DIVIDED BY THE MARKET AREA'S TOTAL PATIENT DAYS FOR THE 12-MONTH PERIOD MOST RECENTLY AVAILABLE THROUGH THE MICHIGAN INPATIENT DATABASE.

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

MARKET SHARE	POINTS AWARDED
APPLICANT WITH HIGHEST MARKET SHARE	10 PTS

ALL OTHER APPLICANTS	APPLICANT"S MARKET SHARE DIVIDED BY THE HIGHEST APPLICANT'S MARKET SHARE IN THE COMPARE GROUP, THEN MULTIPLIED BY 7
EXAMPLE: THE HIGHEST APPLICANT HAS 22.5% OF POPULATION	10 POINTS
APPLICANT WITH 20.0% MARKET SHARE	(20.0 ÷ 22.5) X 7 = 6.2 is 6 POINTS
APPLICANT WITH 15.6% MARKET SHARE	(15.6 ÷ 22.5) X 7 = 4.9 is 5 POINTS

~~The source for calculations under this criterion is the MIDB.~~ FOR PURPOSES OF EVALUATING THIS CRITERION, AN APPLICANT SHALL SUBMIT PATIENT DAYS BY ZIPCODE FOR EACH CURRENTLY LICENSED MICHIGAN HOSPITAL UNDER COMMON OWNERSHIP OR CONTROL USING THE MOST RECENT 12-MONTHS OF DATA AVAILABLE THROUGH THE MIDB AT THE TIME OF THE SUBMISSION OF THE CON APPLICATION. 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. MARKET SHARE PERCENTAGES SHALL BE ROUNDED TO THE NEAREST 1/10 (E.G. 5.3%), AND POINTS AWARDED SHALL BE ROUNDED TO THE NEAREST WHOLE NUMBER, I.E. NUMBERS ENDING IN .5 OR HIGHER, ROUND UP, AND NUMBERS ENDING IN .4 OR LOWER, ROUND DOWN.

(4) IF THE COMPARATIVE REVIEW GROUP INVOLVES A LIMITED ACCESS AREA, EACH 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.

% OF POPULATION WITHIN 30 (OR 60) MINUTE TRAVEL TIME OF PROPOSED SITE	POINTS AWARDED
APPLICANT WITH HIGHEST PERCENT OF POPULATION	10 PTS
ALL OTHER APPLICANTS	APPLICANT'S PERCENTAGE OF POPULATION DIVIDED BY THE HIGHEST APPLICANT'S PERCENTAGE OF POPULATION, THEN MULTIPLIED BY 7
EXAMPLE: THE HIGHEST APPLICANT HAS 22.5% PERCENT OF POPULATION	10 POINTS
APPLICANT WITH 20.0% PERCENT OF POPULATION	(20.0 ÷ 22.5) X 7 = 6.2 is 6 POINTS
APPLICANT WITH 15.6% PERCENT OF POPULATION	(15.6 ÷ 22.5) X 7 = 4.9 is 5 POINTS

PERCENTAGES OF POPULATION SHALL BE ROUNDED TO THE NEAREST 1/10 (E.G. 21.2%) AND POINTS AWARDED SHALL BE ROUNDED TO THE NEAREST WHOLE NUMBER, I.E. NUMBERS ENDING IN .5 OR HIGHER, ROUND UP, AND NUMBERS ENDING IN .4 OR LOWER, ROUND DOWN.

Section 13. ~~**Review standards for comparative review of a limited access area**~~

~~Sec. 13. (1) Any application subject to comparative review, under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and reviewed comparatively with other applications in accordance with the CON rules.~~

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

~~(3)(a) A qualifying project will be awarded points based on the percentile ranking of the applicant's uncompensated care volume as measured by percentage of gross hospital revenues as set forth in the following table. For purposes of scoring, the applicant's uncompensated care will be the cumulative of all currently licensed Michigan hospitals under common ownership or control with the applicant. The source document for the calculation shall be the most recent Cost Report submitted to MDCH MDHHS 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 MDHHS 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 % of population~~
~~30 (or 60) minute travel covered x 15 (total pts~~
~~time of proposed site 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 14.~~ Requirements for approval -- acquisition of AN EXISTING hospital OR RENEW THE LEASE OF AN EXISTING HOSPITAL

Sec. ~~14~~13. AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING HOSPITAL OR RENEW THE LEASE OF AN EXISTING HOSPITAL MUST MEET THE FOLLOWING AS APPLICABLE:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(d) Subsection (2) shall not apply to excluded hospitals OR TO THOSE APPLICANTS APPLYING UNDER SECTION 1*3*(3).

(3) AN APPLICANT PROPOSING TO RENEW THE LEASE FOR AN EXISTING HOSPITAL SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE NEEDED HOSPITAL BED SUPPLY FOR THE HOSPITAL GROUP IN WHICH THE HOSPITAL IS LOCATED, IF ALL OF THE FOLLOWING REQUIREMENTS ARE MET:

(a) THE LEASE RENEWAL WILL NOT RESULT IN A CHANGE IN BED CAPACITY.

(b) THE LICENSED SITE DOES NOT CHANGE AS A RESULT OF THE LEASE RENEWAL.

(4) SECTION 13(3) DOES NOT APPLY TO RENEWAL OF LEASE FOR LTAC HOSPITAL, IRF HOSPITAL OR ALCOHOL AND SUBSTANCE ABUSE HOSPITAL WITHIN AN EXISTING LICENSED, HOST HOSPITAL UNDER SECTION 6(2).

Section ~~15~~14. Requirements for approval – all applicants

Sec. ~~15~~14. (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 COMMUNITY AND Health Systems within ~~the Department of Licensing and Regulatory Affairs~~LARA. 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~~LARA 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 COMMUNITY AND Health Systems or, if applicable, the Centers for Medicare and Medicaid Services.

(4) THE APPLICANT CERTIFIES THAT THE REQUIREMENTS FOR HOSPITALS FOUND IN THE MINIMUM DESIGN STANDARDS FOR HEALTH CARE FACILITIES OF MICHIGAN, REFERENCED IN SECTION 20145 (6) OF THE PUBLIC HEALTH CODE, ACT 368 OF 1978, AS AMENDED, OR ANY FUTURE VERSIONS, AND ARE PUBLISHED BY LARA, WILL BE MET WHEN THE ARCHITECTURAL BLUEPRINTS ARE SUBMITTED FOR REVIEW AND APPROVAL BY LARA.

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

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 November 1, 2014, 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)(~~x~~y) of these standards, and this appendix shall be updated accordingly.

LIMITED ACCESS AREA	BED NEED	PREDICTED PATIENT DAYS
1 Upper Peninsula	196	51,102
2 West Northern Lower Peninsula	310	84,639
3 East/Central Northern Lower Peninsula	127	31,383

Sources:

1) Michigan State University
   Department of Geography
   Acute Care Hospital Bed Need and Limited Access Areas – 2014 Update
   August 6, 2014

2) Section 4 of these standards

ICD-9-CM TO ICD-10-CM Code Translation

ICD-9 CODE	Description	ICD-10 Code	Description
290 through 319	Psychiatric Patients	F01.50-F99	Mental, Behavioral, and Neurodevelopmental Disorders

"ICD-9-CM Code" means the disease codes and nomenclature found in the International Classification of Diseases - 9th Revision - Clinical Modification, prepared by the Commission on Professional and Hospital Activities for the U.S. National Center for Health Statistics.

"ICD-10-CM Code" means the disease codes and nomenclature found in the International Classification of Diseases - 10th Revision - Clinical Modification, National Center for Health Statistics.

CATHOLIC HEALTHCARE INTERNATIONAL FOUNDATION †

Uniting Healthcare with Holiness to Relieve Suffering

Casa USA: *Replicating St. (Padre) Pio's Healthcare Model in America*

Presented To:

Michigan CON Commission
Lansing, Michigan
March 27th, 2018

The Casa USA in Michigan

- Unique Considerations
  - International collaboration with Vatican-owned hospital
  - National profile, outreach, affiliation & catchment
  - Unique model – "*Home for the Relief of Suffering"*
    - Emphasis on serving the "most vulnerable"
  - *"The"* model of Catholic healthcare for the future in US
    - Model to be emulated nationally
      - Source of national affiliation of Catholic hospitals & providers
  - New affiliated medical school in same charism – *"School for the Relief of Suffering"*
  - Replica pilgrim shrine on campus – "*Santa Maria delle Grazie"*
    - Will draw devotees of St. Pio & dedicated pilgrims from around the world
  - Very specific "Mission Focused" vision
    - Not part of large system looking to establish or expand local market share

The Casa USA in Michigan

- Our Prayerful Request of the CON Commission
  - Consider approval of our unique request separate from existing bed need standards for Michigan
    - Independent & very focused regional entity & plan
      - No risk of "slippery slope" ambitions of large systems
    - Nothing similar exists in Michigan…or the US
      - Unprecedented religious mission for Catholic healthcare delivery in the US
        - » Combined with new pilgrim shrine and uniquely focused medical school
    - Privately funded venture through philanthropy by supporters
      - Will not increase healthcare costs in the State of Michigan
      - Will care for vulnerable & neglected populations
      - Philanthropic infrastructure will assure solvency & ability to sustain mission
    - Will further enhance image of Michigan as national leader in healthcare delivery
    - Positive economic impact
      - Significant increase in regional professional jobs, housing, commerce, etc.
      - Shrine will be a national/international draw for pilgrims & regional tourism dollars
      - Medical school will bring students & future physicians to the region from around the world
    - Enhancements to the region will actually benefit existing providers
    - The special nature of this request in no way undermines the excellent integrity of the CON Commission & its work

St. (Padre) Pio & His *"Work"*

- Who is St. Pio?
  - Capuchin friar, stigmatist, confessor, miracle worker, saint, founder of the Casa Hospital Italy, etc.
- Casa Sollievo Della Sofferenza – *"The Home For The Relief Of Suffering"*
  - A Clinic for the Body & the Soul
  - Vatican owned
  - A unique model of faithful Catholic healthcare delivery
  - The best technology & highest quality of care

St. (Padre) Pio & His *"Work"*

- Padre Pio Prayer Groups
  - Prayer As The Foundation Of The *"Work"*
    - 3,417 prayer groups in 65 countries
    - 125 US Padre Pio Prayer Groups
  - Formally chartered international & national network of support already in place
    - Fr. Francis Sariego, OFM Cap. – US Prayer Groups Director & Director of Catholic Healthcare International

St. (Padre) Pio & His *"Work"*

The Cappuccini Church when Padre Pio arrived in San Giovanni Rotondo (1916)

Attachment K

Casa Hospital Inauguration Day
May 5, 1956

Attachment K

Mass on the Inauguration Day of the Casa Hospital

Attachment X

The Convent, Church & Hospital Campus 1958

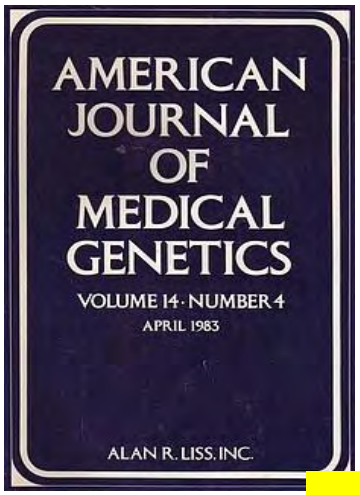
The Convent, Church & Casa Hospital Campus Today

The Convent, Church & Casa Hospital Campus Today

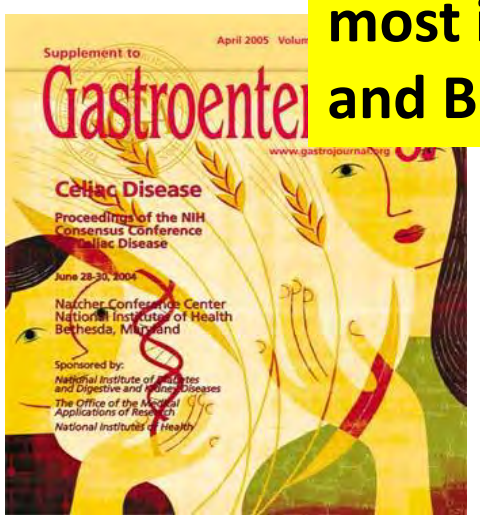
Attachment K

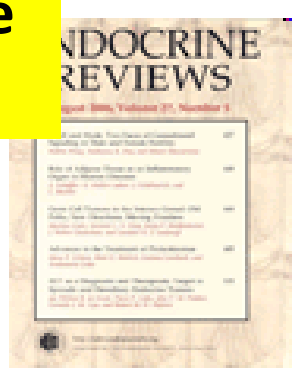
Attachment K

Scientific Productivity



Nearly 150 yearly publications on the most important journals in Medicine and Biology

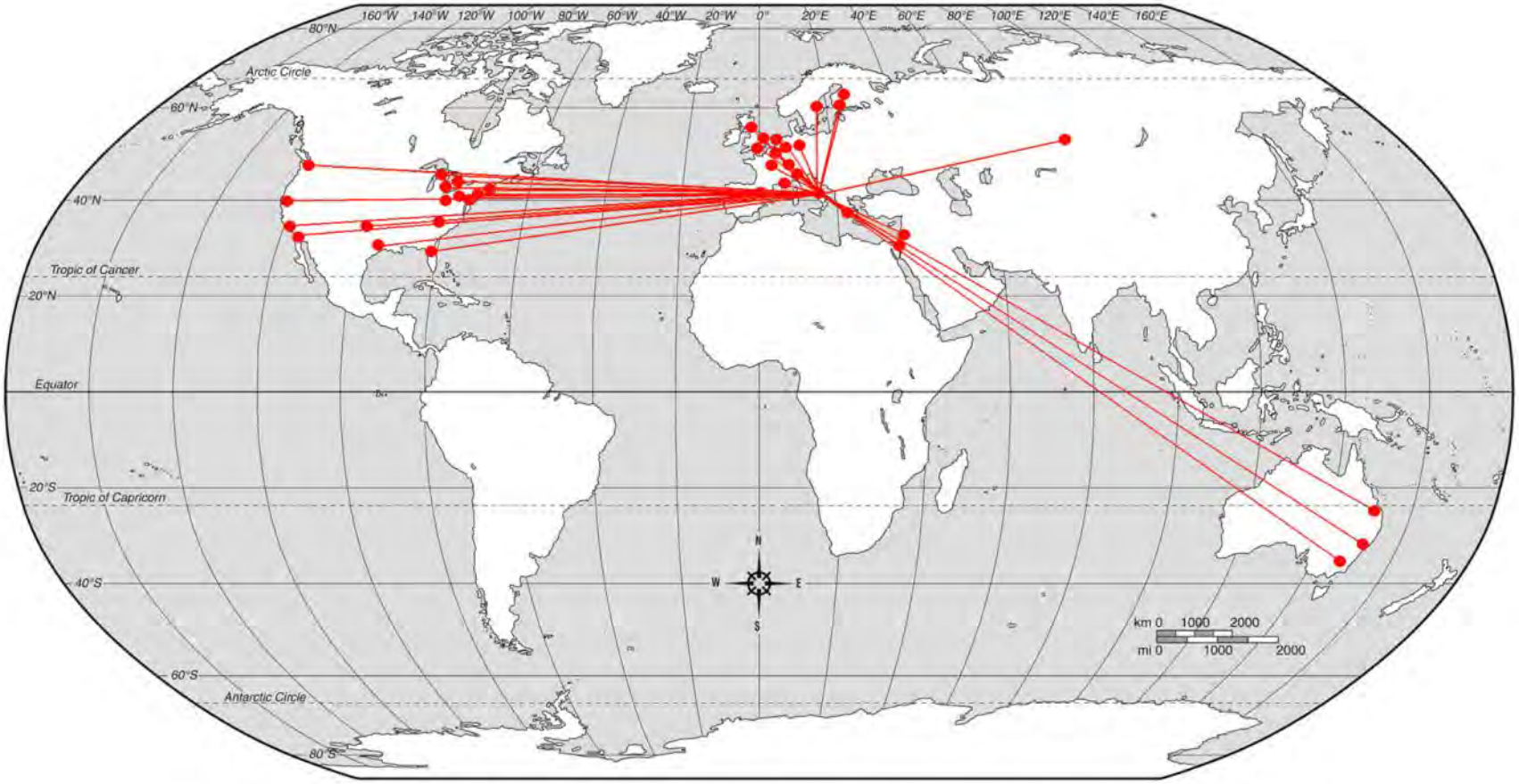




Attachment K

La Dimensione Internazionale della Ricerca Scientifica

Le collaborazioni scientifiche internazionali dell'Istituto di Ricovero e Cura a Carattere Scientifico "Casa Sollievo della Sofferenza"



"Un Centro di studi intercontinentale dovrà coadiuvare i sanitari a perfezionare la loro cultura professionale"

San Pio da Pietrelcina

in occasione del primo anniversario della Casa Sollievo della Sofferenza, 5 maggio 1957

"If this Home were just solace for bodies, it would only amount to a model clinic, built by the means of your extraordinarily generous charity."

"On the contrary, it is pushed to be an active reminder of the love of God, through the call to charity."

- Padre Pio

Our Vision

"The Casa Sollievo della Sofferenza should therefore be the first link in a great chain. It should be the model for many other, innumerable Casa's with the same name and above all the same spirit, which must bring love to all of humanity. A program which would make us tremble with awe, if it was not inspired by God who is above all love!"

- ***Dr. Guglielmo Sanguinetti*** *– A Founder & Director of Implementation of the Casa*
  (Excerpt from the July 1950 issue of La Casa Sollievo della Sofferenza)

Casa Sollievo della Sofferenza

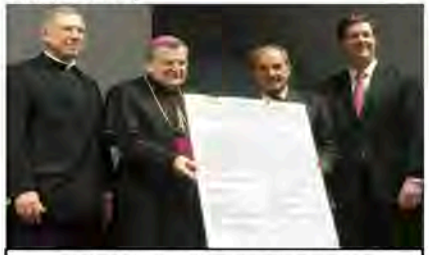
CHI CATHOLIC HEALTHCARE INTERNATIONAL

Collaboration Agreement

On October 1, 2009 a formal Collaboration Agreement was signed by the leadership of Padre Pio's hospital in Italy (Casa Sollievo della Sofferenza) and Catholic Healthcare International.

Key Collaboration Points:

- **Parties to the Agreement:**
  - **Casa Sollievo della Sofferenza (CSS)** – Established by Padre Pio, his *"Work"*, Vatican owned, & based in San Giovanni Rotondo, Italy.
  - **Catholic Healthcare International (CHI)** – U.S. nonprofit with the vision to implement these collaborative initiatives with CSS.
  - **Signed By: Cardinal (Archbishop) Raymond Burke** (Patron of the Sovereign Military Order of Malta), **Dott. Domenico Crupi** (Vice President & Director General of CSS), **Msgr. Vernon Gardin** (Director of CHI) & **Jere Palazzolo** (President & Director of CHI)



Collaboration Signing Celebration
Msgr. Vernon Gardin, Cardinal Raymond Burke, Dott. Domenico Crupi & Jere Palazzolo

- **Objectives of The Collaboration Initiatives:**
  - Duplicate Padre Pio's *Home For The Relief of Suffering* (CSS) in the United States and other areas around the world.
  - Establish a Catholic Medical School fully faithful to the Magisterium of the Catholic Church & in the charism of Padre Pio to form physicians and healthcare providers to practice as faithful Catholics in the secular world.
  - Emulate the structure, name, operation, organization, etc. as closely as possible to that of Padre Pio's Casa.
  - Maintain absolute loyalty to the Magisterium of the Catholic Church.
  - Operate the new network of Casa's as "Beacons of Light" in a secular world…*"Clinics for the Body & the Soul"* for our *"guests"* (From the words of Padre Pio).

Our Vision

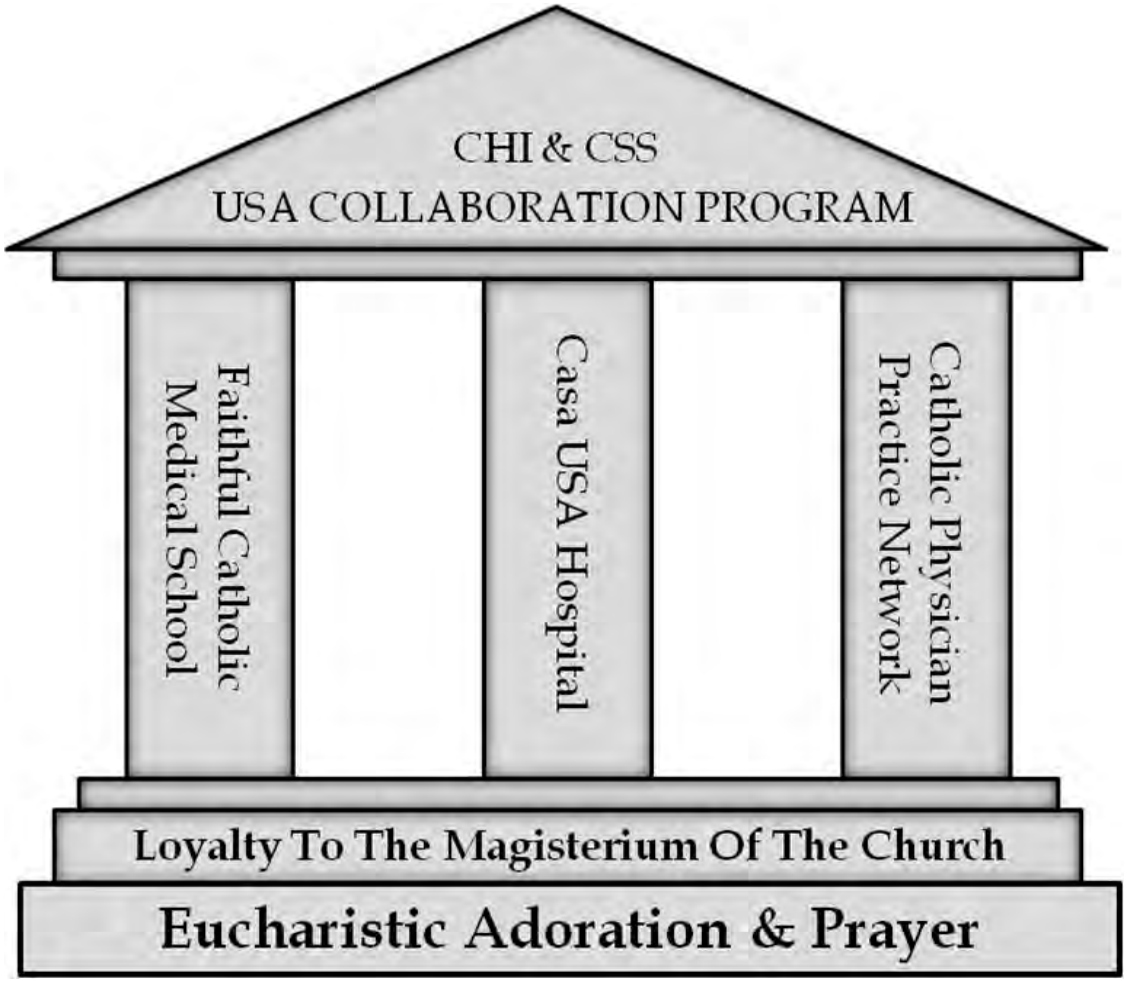
"The Casa Sollievo della Sofferenza should therefore be the first link in a great chain. It should be the model for many other, innumerable Casa's with the same name and above all the same spirit, which must bring love to all of humanity. A program which would make us tremble with awe, if it was not inspired by God who is above all love!"

Dr. Guglielmo Sanguinetti *– A Founder & Padre Pio's Director of Implementation for CSS*
(Excerpt from the July 1950 issue of La Casa Sollievo della Sofferenza)

Attachment K

Formal Collaboration Signing Program

Casa USA



Three Pillar Program

Our First Fruits

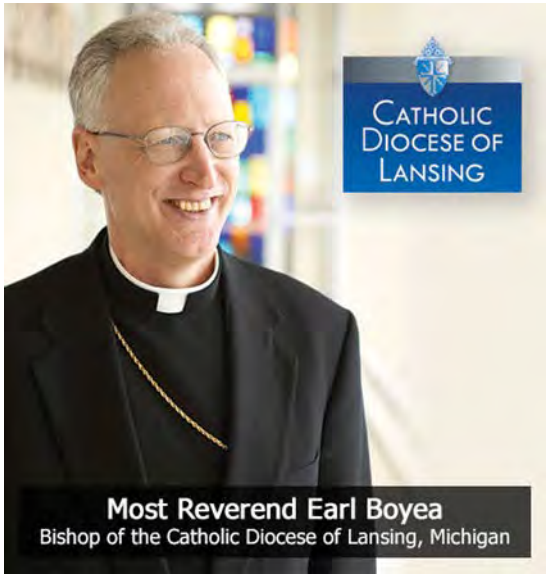
Attachment K

Casa San Pio – Stanton, KY

Casa USA – Diocese of Lansing, Michigan

CATHOLIC HEALTHCARE INTERNATIONAL
Uniting Healthcare with Holiness to Relieve Suffering

CASA SOLLIEVO DELLA SOFFERENZA • SAN GIOVANNI ROTONDO •

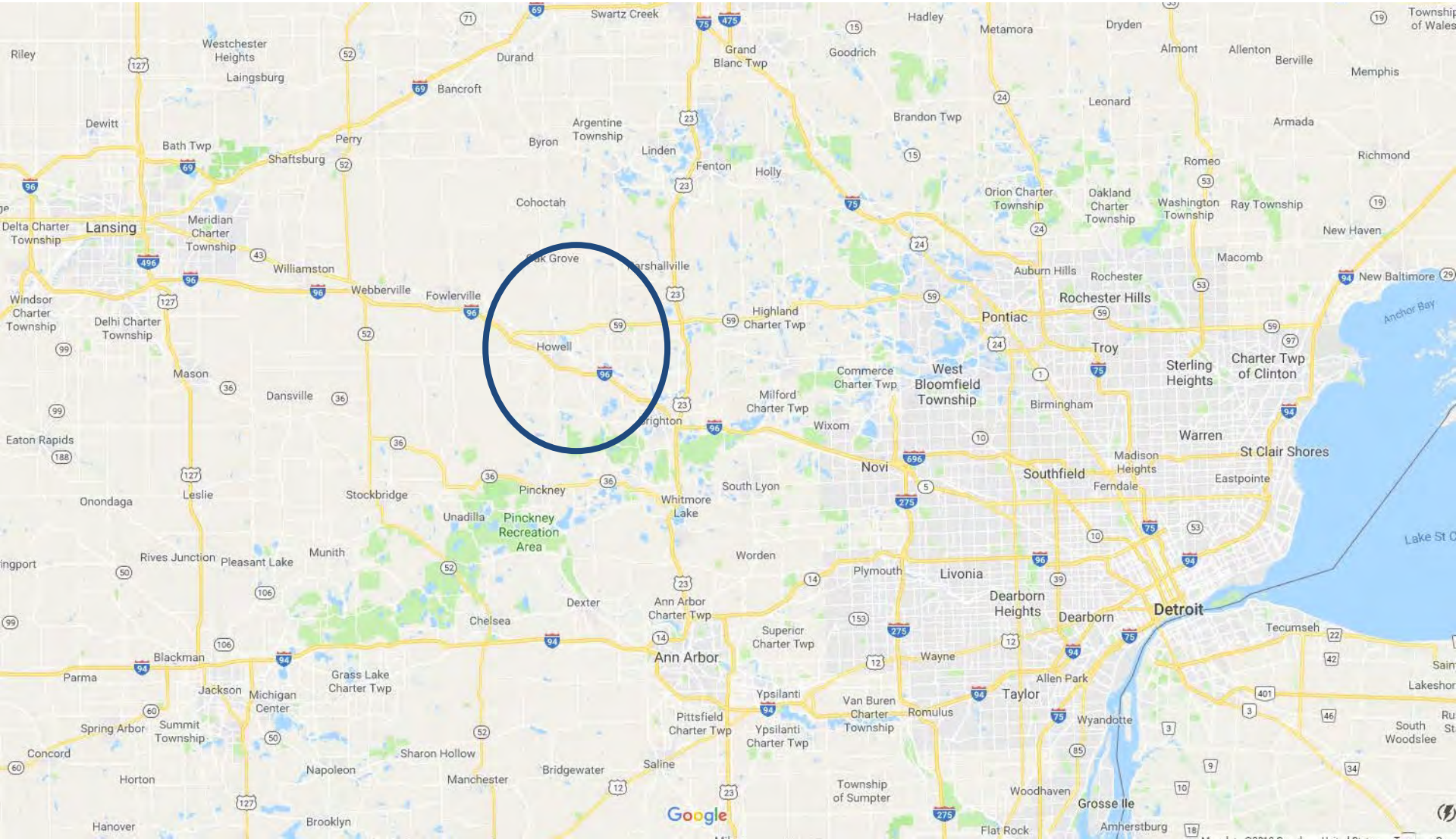


Terri Schiavo Life&Hope Network

CHRIST MEDICUS FOUNDATION
CURO

Attachment K

Casa USA Campus – Diocese of Lansing
Howell, Michigan



Land Donated by Diocese of Lansing
Casa USA Campus – Howell, Michigan

Replica of St. Pio's Casa Hospital

Attachment K

"Home for the Relief of Suffering"

Pilgrimage Shrine – Howell, MI

Attachment K

Duplicate of Santa Maria Delle Grazie – Padre Pio's Church

"It is prayer, this united force and strength of all good people, which moves the world, which renews consciences, which sustains the Casa and which comforts the suffering, which heals the sick, which sanctifies Work…"

- Padre Pio

Faithful Catholic Medical School

Attachment K

"School for the Relief of Suffering"

Attachment K

The Casa USA in Michigan

- Our Prayerful Request of the CON Commission
  - Consider approval of our unique request separate from existing bed need standards for Michigan
    - Independent & very focused regional entity & plan
      - No risk of "slippery slope" ambitions of large systems
    - Nothing similar exists in Michigan…or the US
      - Unprecedented religious mission for Catholic healthcare delivery in the US
        - » Combined with new pilgrim shrine and uniquely focused medical school
    - Privately funded venture through philanthropy by supporters
      - Will not increase healthcare costs in the State of Michigan
      - Will care for vulnerable & neglected populations
      - Philanthropic infrastructure will assure solvency & ability to sustain mission
    - Will further enhance image of Michigan as national leader in healthcare delivery
    - Positive economic impact
      - Significant increase in regional professional jobs, housing, commerce, etc.
      - Shrine will be a national/international draw for pilgrims & regional tourism dollars
      - Medical school will bring students & future physicians to the region from around the world
    - Enhancements to the region will actually benefit existing providers
    - The special nature of this request in no way undermines the excellent integrity of the CON Commission & its work

Attachment K

"This evening my earthly Work has begun. I bless you and all those that will contribute to the Work which will become bigger and more beautiful."

- *Padre Pio as he first met with his leadership team to discuss his vision for the Casa*

CERTIFICATE OF NEED

1st Quarter Compliance Report to the CON Commission

October 1, 2017 through September 30, 2018 (FY 2018)

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	69	69
Approved projects contacted on or before anniversary date	55	55
Approved projects completed on or before 1-year follow up	80%	
CON approvals expired	19	19
Total follow up correspondence sent	179	179
Total approved projects still ongoing	300	

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 proposes conducting statewide compliance reviews for Neonatal Intensive Care Unit (NICU) beds, Special Care Nursery (SCN) services, Computed Tomography (CT) scanner services and Open Heart Surgery (OHS) services utilizing 2016 CON Annual Survey data. The Department is in the process of evaluating annual survey data, review standard requirements, and CON approved facilities for these selected services to identify the facilities for compliance investigations. The finding of the statewide compliance reviews will be reported to the CON Commission at a later date.

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

CERTIFICATE OF NEED

1st Quarter Program Activity Report to the CON Commission

October 1, 2017 through September 30, 2018 (FY 2018)

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	60	N/A	60	N/A
Letters of Intent Processed within 15 days	60	100%	60	100%
Letters of Intent Processed Online	60	100%	60	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	82	N/A	82	N/A
Applications Processed within 15 Days	82	100%	82	100%
Applications Incomplete/More Information Needed	57	70%	57	70%
Applications Filed Online*	78	100%	78	100%
Application Fees Received Online*	17	22%	17	22%

* 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	59	100%	59	100%
Substantive Applications	18	100%	18	100%
Comparative Applications	0	N/A	0	N/A

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

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	21	100%	21	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	41	N/A	41	N/A
FOIA Requests Processed on Time *	41	100%	41	100%
Number of Applications Viewed Onsite	0	N/A	0	N/A

FOIA – Freedom of Information Act.

*Request processed within 5 days or an extension filed.

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

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.

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

Attachment N

	2017						2018					
	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March	April	May	June
Commission Meetings			Meeting			Meeting		Special Meeting	Meeting			Meeting
Bone Marrow Transplantation (BMT) Services				Public Comment for 2018 Review				Discussion	Draft Language Presented/Potential Proposed Action		Public Hearing	Report/ Final Action
Cardiac Catheterization Services	SAC Meeting	SAC Meeting	SAC Meeting/ Report	SAC Meeting	SAC Meeting	SAC Meeting/ Report			Report/Draft Language Presented/Potential Proposed Action		Public Hearing	Report/ Final Action
Hospital Beds	SAC Meeting	SAC Meeting	SAC Meeting/ Report	SAC Meeting	SAC Meeting	SAC Meeting/ Report			Report/Draft Language Presented/Potential Proposed Action		Public Hearing	Report/ Final Action
Megavoltage Radiation Therapy (MRT) Services/Units								Discussion/Report; SAC Nomination & Selection Period starts	SAC Nomination & Selection Period			
Open Heart Surgery (OHS)									Report/ Draft Language Presented/Potential Proposed Action		Public Hearing	Report/ Final Action
Psychiatric Beds and Services				Public Comment for 2018 Review				Discussion; SAC Nomination & Selection Period starts	SAC Nomination & Selection Period			
Urinary Extracorporeal Shock Wave Lithotripsy Services		Public Hearing	Report/ Potential Final Action			Report/Draft Language Presented/Proposed Action	Public Hearing		Report/ Final Action			
New Medical Technology Standing Committee	Department Monitoring					Department Monitoring			Department Monitoring			

For Approval March 27trg, 2018 The CON Commission may revise this work plan at each meeting. For information about the CON Commission work plan or how to be notified of CON Commission meetings, contact the Michigan Department of Health and Human Services (MDHHS), Policy, Planning & Legislative Services, Office of Planning, 5th Floor South Grand Bldg., 333 S. Grand Ave., Lansing, MI 48933, 517-335-6708, **www.michigan.gov/con**.

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

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	June 2, 2014	2019
Bone Marrow Transplantation Services	September 29, 2014	2021
Cardiac Catheterization Services	September 14, 2015	2020
Computed Tomography (CT) Scanner Services	December 9, 2016	2019
Heart/Lung and Liver Transplantation Services	September 28, 2012	2021
Hospital Beds	March 20, 2015	2020
Magnetic Resonance Imaging (MRI) Services	October 21, 2016	2021
Megavoltage Radiation Therapy (MRT) Services/Units	September 14, 2015	2020
Neonatal Intensive Care Services/Beds (NICU)	December 9, 2016	2019
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	March 20, 2015	2019
Open Heart Surgery Services	June 2, 2014	2020
Positron Emission Tomography (PET) Scanner Services	September 14, 2015	2020
Psychiatric Beds and Services	December 9, 2016	2018
Surgical Services	December 22, 2014	2020
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	December 22, 2014	2019

*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.