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

Thursday, September 20, 2018

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

APPROVED MINUTES

I. Call to Order & Introductions

Chairperson Falahee called the meeting to order at 9:36 a.m. and introduced Commissioners Dood and Oca. Chairperson Falahee also acknowledged and thanked former Commissioners Tomatis and Clarkson.

A. Members Present:

James B. Falahee, Jr., JD, Chairperson
Thomas Mittelbrun, Vice-Chairperson
Denise Brooks-Williams
Tressa Gardner, DO
Debra Guido-Allen, RN
Robert Hughes
Melanie LaLonde
Lindsey Dood

B. Members Absent:

Stewart Wang, MD
Melisa Oca, MD
Amy McKenzie, MD

C. Department of Attorney General Staff:

Carl Hammaker

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

Tulika Bhattacharya
Amber Myers
Beth Nagel
Tania Rodriguez

II. Review of Agenda

Motion by Commissioner Hughes, seconded by Commissioner Mittlebrun to approve the agenda as presented. Motion carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of June 14, 2018

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

V. Open Heart Surgery (OHS) Services – Public Hearing Summary

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

A. Public Comment

None

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner Mittlebrun 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 8 - Yes, 0 - No, and 0 - Abstained.

VI. Cardiac Catheterizations Services – Public Hearing Summary

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

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner Mittlebrun to take final action on the language (Attachment D) as presented and move forward to the JLC and Governor for the 45-day review period. Motion carried in a vote of 8 - Yes, 0 - No, and 0 - Abstained.

VII. Hospital Beds – Re-calculation of Bed Need Numbers – Setting the Effective Date

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

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Mittlebrun, seconded by Commissioner Hughes to set effective date of October 1 for the updated bed need. Motion carried in a vote of 8 - Yes, 0 - No, and 0 - Abstained.

VIII. Review Draft of CON Commission Biennial Report to JLC

Ms. Nagel gave an overview of the biennial report (Attachment F).

IX. Megavoltage Radiation Therapy Services/Units Standard Advisory Committee (MRTSAC) Interim Report (Written Only)

Chairperson Falahee mentioned the written report (Attachment G) from Brian Kastner, MD, MRTSAC Chairperson.

Discussion followed. The Department will provide feedback to the MRTSAC stating that the Commission would like to know more about cost, quality and access of decision to go from 8,000 to 4,000 ETVs in the maintenance volume.

X. Psychiatric Beds and Services Workgroup Interim Report (Written Only)

Chairperson Falahee mentioned the written report (Attachment H) from Laura Hirshbein, MD, PhD, Psychiatric Beds and Services Workgroup Chairperson.

XI. Legislative Report

None.

XII. Administrative Update

A. Planning & Access to Care Section Update

Ms. Nagel provided an update.

B. CON Evaluation Section Update

Ms. Bhattacharya provided an update on the following items:

1. Compliance Report (Attachment I)
2. Quarterly Performance Measures (Attachment J)

XIII. Legal Activity Report

Mr. Hammaker provided an update on the CON legal activity (Attachment K).

XIV. Future Meeting Dates:

December 6, 2018, January 31, 2019 (Special Commission Meeting), March 21, 2019, June 13, 2019, September 19, 2019, and December 5, 2019

XV. Public Comment

Caroline Fuller – American Surgical Centers (Attachment L)

XVI. Review of Commission Work Plan

Ms. Nagel provided an overview of the changes to the Work Plan (Attachment M).

A. Commission Discussion

None.

B. Commission Action

Motion by Commissioner Guido-Allen, seconded by Commissioner Mittlebrun to accept the Work Plan as presented with updates from today's meeting. Motion carried in a vote of 8 - Yes, 0- No, and 0- Abstained.

XVII. Adjournment

Motion by Commissioner Guido Allen, seconded by Commissioner Lalonde to adjourn the meeting at 10:12 a.m. Motion Carried in a vote of 8 - Yes, 0 - No, and 0 - Abstained.

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

Date: July 31, 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 Open Heart Surgery (OHS) 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 OHS Services Standards at its June 14, 2018 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed OHS Services Standards on July 19, 2018. Written testimony was accepted for an additional seven days after the hearing. Testimony was received from one organization.

Written Testimony:

1.) Marlena Hendershot, Sparrow Health System

- Supports the proposed language.

Department Recommendation:

The Department supports the language as presented at the June 14, 2018 CON Commission meeting.

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 THE EXISTING OHS SERVICE IS LOCATED AND WITHIN 5 MILES OF THE EXISTING OHS SERVICE LOCATION IF LOCATED IN A METROPOLITAN STATISTICAL AREA COUNTY, OR WITHIN 10 MILES OF THE EXISTING OHS SERVICE LOCATION IF LOCATED IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.

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

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

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 ~~89~~9. Methodology for computing the number of adult open heart surgical cases

Sec. ~~89~~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 ~~89~~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 ~~89~~9(1)(a)(ii) will be divided by the number of discharges identified in subsection ~~89~~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

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

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

APPENDIX E

ICD-9-CM TO ICD-10-CM CODE TRANSLATION FOR APPENDIX B

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
745.0 – 747.99	Congenital Anomalies	P29.3	Persistent Fetal Circulation
		Q20.0-Q28.9	Congenital Malformations of the Circulatory System
164.1	All Other Heart Conditions	C38.0	Malignant Neoplasm of Heart
		C45.2	Mesothelioma of Pericardium
212.7	All Other Heart Conditions	D15.1	Benign Neoplasm of Heart
390 - 429.99	All Other Heart Conditions	A01.02	Typhoid Fever with Heart Involvement
		A18.84	Tuberculosis of Heart
		I00-I09.9	Rheumatic Fever/Heart Diseases
		I10-I15.9	Hypertensive Diseases
		I20.0-I25.9	Ischemic Heart Diseases
		I26.01-I28.9	Pulmonary Heart Disease/Pulmonary Circulation Diseases
		I30.0-I52	Other Forms of Heart Disease
		I97.0-197.191	Intraoperative/Postprocedural Cardiac Complications
		N26.2	Page Kidney
		R00.1	Bradycardia, Unspecified
		T80.0XXA	Air Embolism Following Infusion, Transfusion and Therapeutic Injection, Initial Encounter
		T81.718A	Complication of Other Artery Following a Procedure, Not Elsewhere Classified, Initial Encounter
		T81.72XA	Complication of Vein Following a Procedure, not Elsewhere Classified, Initial Encounter
		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

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

Date: August 20, 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 Cardiac Catheterization 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 Cardiac Catheterization Services Standards at its June 14, 2018 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed Cardiac Catheterization Services Standards on July 19, 2018. Written testimony was accepted for an additional seven days after the hearing. Testimony was received from four organizations and two individuals.

Written Testimony:

1.) Henry Kim, MD, Henry Ford Health System (HFHS)

- Supports the proposed language. "Specifically, the revised language allowing pacemaker and ICD implantation only be done in hospitals with Cardiac Catherization service approval and the relocation language which aligns relocation of Cardiac Catherization services in conjunction with an Open Heart services program."

2.) Randy Lieberman, MD

- Urges the CON Commission to allow pacemaker and ICD placement to be performed in an ASC setting as has been allowed in other states for many years.

3.) Tracey Burke, MBA, MSA, RVT, RDMS, Spectrum Health

- Supports the proposed language. Specifically, the "language to keep pacemakers and implantable cardioverter defibrillator implant procedures in licensed hospitals."

4.) Tony Murry

- Supports device implantation and generator changes (Pacemakers & Defibrillator) at CMS-certified, accredited ambulatory surgery centers (ASCs).

5.) Marlena Hendershot, Sparrow Health System

- Supports the proposed language including the language to keep ICD and Pacemaker implantations within a licensed hospital with cardiac catheterization services.

6.) American Surgical Centers II, LLC

- Recommends allowing permanent pacemakers and ICD implant placement to be performed in an ASC setting.

Department Recommendation:

The Department supports the language as presented at the June 14, 2018 CON Commission meeting.

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 AND HAS DIAGNOSTIC CARDIAC CATHETERIZATION CON APPROVAL.

(~~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.

(~~nw~~) "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.

(~~ox~~) "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.

(~~py~~) "Procedure equivalent" means a unit of measure that reflects the relative average length of time one patient spends in one session in a CARDIAC CATHETERIZATION laboratory based on the type of procedures being performed. IF A DIAGNOSTIC AND THERAPEUTIC PROCEDURE IS PERFORMED IN THE SAME SESSION, THE HIGHER PROCEDURE EQUIVALENT WEIGHTING WILL BE USED TO EVALUATE UTILIZATION.

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

(~~qaa~~) "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 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.

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

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

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

(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 AND WITHIN 5 MILES OF THE EXISTING OHS AND CARDIAC CATHETERIZATION SERVICE IF LOCATED IN A METROPOLITAN STATISTICAL AREA COUNTY OR WITHIN 10 MILES OF THE EXISTING OHS AND CARDIAC CATHETERIZATION SERVICE IF LOCATED IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.

(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/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 THERAPEUTIC PROCEDURE, CARDIAC BIOPSY, INTRA-CARDIAC ECHOCARDIOGRAPHY (ICE),	1.5	2.7

Procedure Type	DESCRIPTION	Procedure equivalent	
		Adult	Pediatric
	DIAGNOSTIC ELECTROPHYSIOLOGY STUDY, ANGIOGRAPHY IN THE PERIPHERAL ARTERIAL OR VENOUS CIRCULATION		
Therapeutic cardiac catheterization~~/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.

Acute Care Hospital Bed Need and Limited Access Areas
2018 Update

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Summary

This report provides updated results for the Acute Care Hospital Bed Need and Limited Access Areas (LAAs). An increasing trend in patient days over prior years is noted. The LAA map is similar to past implementations. Tables and figures contained within this report are also provided in separate files.

Determination of Needed Hospital Bed Supply

The planning year used for the updated bed need is 2021, five years from the most recent MIDB data (2016). The output of the methodology is found in Table 1. In this analysis, the most recent hospital beds inventory (Dept Inv 2018) is compared to the predicted number of beds needs in 2021. The difference between the actual utilization in 2016 and the predicted utilization in 2021 is also included in Table 1. In 16 of the 33 Hospital Groups, the predicted bed need in 2021 is less than current utilization (2016). In 13 Hospital Groups, the predicted bed need in 2021 was less than current utilization, and in four Hospital Groups, it was the same as the current utilization.

The predicted statewide bed need for 2021 is 18,718 beds, which is slightly more than 2,000 beds greater than the previous estimate (bed need for 2019, calculated in 2016). The rise is attributed to large increases in acute care hospitalization occurring in 2015 and 2016. Figure 1 shows the patient day utilization from 2000 to 2016 and clearly shows the substantial increase in the last two years since the last bed update (which used 2010-2014 data). In the county-level patient day prediction phase of the Bed Need Methodology, 15 out of 84 county units (83 counties plus one “out-of-state” unit) demonstrated a significant positive linear trend in patient day utilization. Only nine counties had a negative linear trend in patient day utilization. No significant linear trend was detected in 60 counties. Despite these increases, all Hospital Groups will continue to have excess hospital beds given the large number of currently licensed beds and the state, overall, is expected to have 6,775 excess beds.

Limited Access Areas

Figure 2 provides the map of the Limited Access Areas. The bed need for each LAA can be found in Table 2, while the zip codes associated with each LAA are listed in Table 3. Based on 2016 hospitalization data, the minimum number of predicted patient days for an underserved area to be considered an LAA was 26,851. This value was calculated using the overall state rate of 0.537 patient days per person and a minimum population of 50,000, per the Review Standards.

Six LAAs were identified in the 2018 update, an increase from the five identified in the 2016 update. LAAs 1, 2, 3, and 5 are nearly identical to the LAAs 1-3 and 5 from the 2016 update (Upper Peninsula, East/Central Northern Lower Peninsula, Northwest Lower Peninsula, and East Southern Lower Peninsula). LAA 4 and LAA 6 were identified as underserved areas in the previous report but were slightly under the patient day threshold to be considered LAAs. A previous LAA (LAA 4 in 2016 report) is now only considered an underserved area, as the predicted patient days value was well beneath the threshold.

Given the increasing trend in patient day utilization in some regions, the identification of additional LAAs is not surprising, especially when considering that the two new LAAs were near the threshold in the 2016 calculation. However, the differences in the LAAs from the previous update could also be due to several reasons not related to health. First, the MSU/UNC team utilized a more recent roads data layer from the Michigan CGI. Minor changes in the roads (e.g., new roads) and/or road speed limits have the potential to affect the size of the underserved areas (outside of a 30-minute drive to the nearest acute care hospital). The team also used an updated Zip Code boundary layer. Minor shifts in the boundaries of Zip Codes could also have affected which Zip Codes are assigned to the underserved areas, which would affect the predicted number of patient days.

Table 1. Bed Need Results for 2018. Source Data: 2012–2016 MIDB. Excess Bed Need is calculated as the difference between Bed Need 2021 and Dept Inv 2018.

HG	ADC 2016	Bed Need 2021	Diff	Diff(%)	Bed Need 2021	Beds 2018	Dept Inv 2018	Excess Bed Need
1	3,058	2,964	*-94*	*-3.07*	2,964	4,070	4,044	1,080
2	2,753	2,827	74	2.69	2,827	3,507	3,507	680
3	1,652	1,687	35	2.12	1,687	2,030	2,030	343
4	1,374	1,292	*-82*	*-5.97*	1,292	1,973	1,973	681
5	1,294	1,287	*-7*	*-0.54*	1,287	1,788	1,783	496
6	248	259	11	4.44	259	375	375	116
7	823	802	*-21*	*-2.55*	802	1,086	1,086	284
8	322	306	*-16*	*-4.97*	306	389	389	83
9	67	64	*-3*	*-4.48*	64	113	113	49
10	730	770	40	5.48	770	899	899	129
11	298	319	21	7.05	319	417	427	108
12	233	184	*-49*	*-21.03*	184	316	316	132
13	64	63	*-1*	*-1.56*	63	237	237	174
14	1,375	1,409	34	2.47	1,409	1,842	1,862	453
15	323	322	*-1*	*-0.31*	322	462	462	140
16	175	170	*-5*	*-2.86*	170	311	311	141
17	134	129	*-5*	*-3.73*	129	237	237	108
18	79	79	0	0.00	79	143	143	64
19	1,208	1,279	71	5.88	1,279	1,441	1,441	162
20	1,134	1,147	13	1.15	1,147	1,708	1,688	541
21	47	47	0	0.00	47	188	188	141
22	62	59	*-3*	*-4.84*	59	192	192	133
23	62	63	1	1.61	63	160	160	97
24	430	426	*-4*	*-0.93*	426	550	550	124
25	167	181	14	8.38	181	227	227	46
26	82	84	2	2.44	84	124	124	40
27	60	64	4	6.67	64	102	102	38
28	222	255	33	14.86	255	314	282	27
29	53	50	*-3*	*-5.66*	50	89	89	39
30	56	50	*-6*	*-10.71*	50	111	111	61
31	72	69	*-3*	*-4.17*	69	107	107	38
32	7	7	0	0.00	7	23	23	16
33	4	4	0	0.00	4	15	15	11
State	**18,668**	**18,718**	**50**	**0.27**	**18,718**	**25,546**	**25,493**	**6,775**

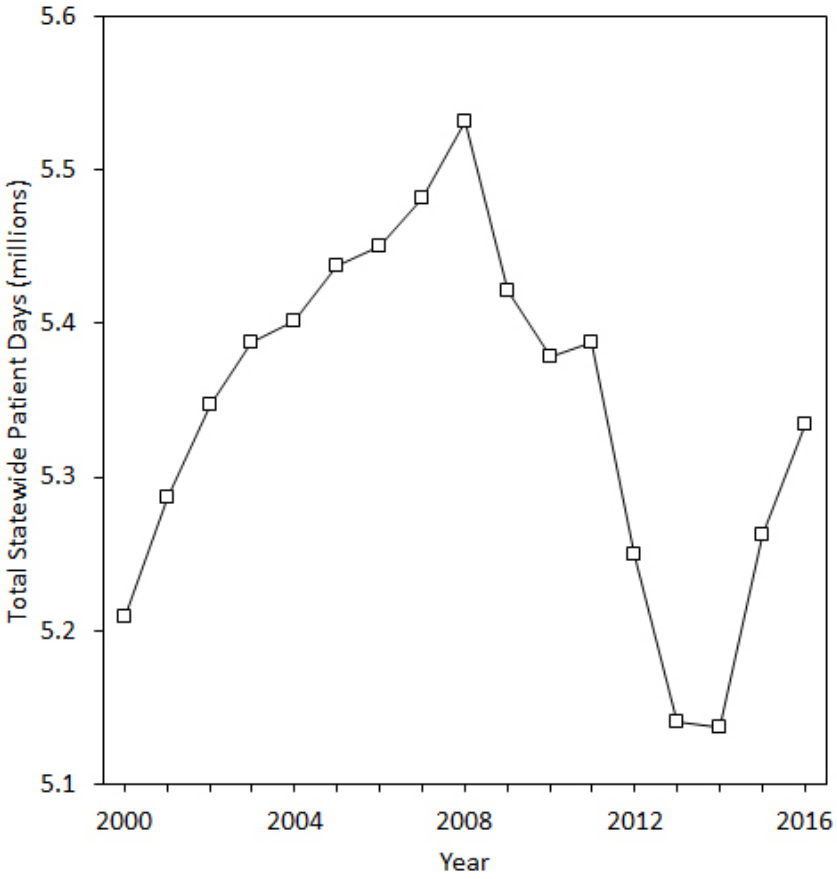
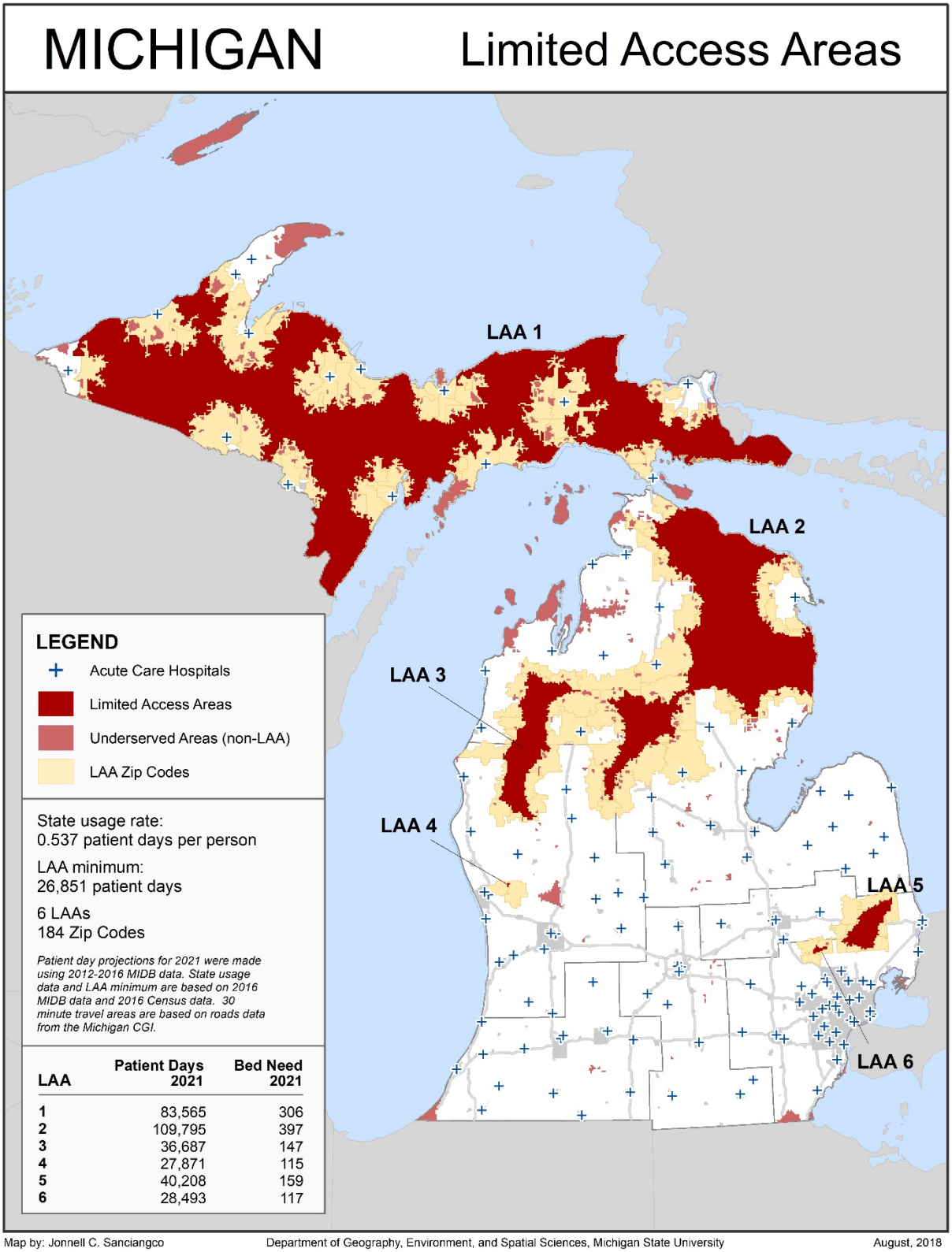


Figure 1. Statewide Patient Days, 2000–2016

Table 2. Bed Need for Limited Access Areas

LAA	Predicted Patient Days	Bed Need 2021
1	83,565	306
2	109,795	397
3	36,687	147
4	27,871	115
5	40,208	159
6	28,493	117



LAA	Patient Days 2021	Bed Need 2021
1	83,565	306
2	109,795	397
3	36,687	147
4	27,871	115
5	40,208	159
6	28,493	117

Figure 2. Limited Access Areas

Table 3. Limited Access Areas, Zip Codes

LAA 1			LAA 2		LAA 3	LAA 4	LAA 5	LAA 6
49710	49829	49885	48619	49651	49304	49442	48002	48348
49715	49831	49886	48621	49665	49309	49451	48003	48371
49719	49833	49887	48624	49667	49402		48005	48462
49725	49834	49891	48625	49679	49411		48006	
49726	49835	49892	48629	49705	49459		48014	
49728	49836	49893	48630	49706	49601		48022	
49736	49837	49895	48632	49709	49619		48041	
49745	49838	49896	48635	49716	49620		48062	
49752	49839	49905	48636	49721	49625		48065	
49760	49840	49910	48647	49738	49633		48097	
49762	49841	49912	48651	49743	49637		48367	
49768	49847	49916	48653	49744	49638		48428	
49774	49848	49919	48654	49746	49643		48444	
49780	49849	49920	48656	49747	49644			
49781	49853	49925	48705	49749	49645			
49801	49854	49935	48721	49751	49649			
49806	49855	49946	48728	49753	49656			
49807	49858	49947	48737	49756	49663			
49812	49861	49948	48738	49759	49668			
49814	49862	49952	48739	49765	49683			
49815	49866	49953	48740	49766	49689			
49816	49868	49958	48742	49769				
49817	49873	49962	48743	49776				
49818	49874	49965	48745	49777				
49820	49878	49967	48750	49779				
49821	49879	49968	48761	49792				
49822	49880	49969	48762	49799				
49825	49881	49970	49305					
49826	49883		49631					
49827	49884		49632					

Attachment F

WORKING DRAFT

STATE OF MICHIGAN

RICK SNYDER,
Governor

Michigan Certificate of Need Commission

SOUTH GRAND BUILDING
333 S. GRAND AVE
LANSING, MI 48933
Phone: (517) 335-6708

Commissioners:
Denise Brooks-Williams
John Dood
James B. Falahee, Jr, JD, Chairperson
Tressa Gardner, DO
Debra Guido-Allen
Robert L. Hughes
Melanie K. Lalonde
Amy McKenzie, MD
Tom Mittelbrun III, Vice-Chairperson
Melisa Oca, MD
Stewart C. Wang

MEMORANDUM

Date: September 20, 2018

To: Joint Legislative Committee (JLC)

From: Certificate of Need (CON) Commission

RE: Recommendations Pertaining to the CON Program

MCL 333.22215(1)(f) requires the CON Commission, by January 1, 2005, and every 2 years after January 1, 2005, to "*make recommendations to the joint committee regarding statutory changes to improve or eliminate the certificate of need program*." In addition to the responsibility of submitting the 2-year report to the JLC, MCL 333.22215(1)(e) of the CON law requires the Commission to "*Annually assess the operations and effectiveness of the certificate of need program based on periodic reports from the department and other information available to the commission*." This report is intended to fulfill these requirements.

To start, we would like to remind the JLC that the CON Commission is composed of 11 volunteers and oversees 15 covered services. The CON Commissioners receive no compensation for their services, other than reimbursement for travel expenses. The CON Commission meets five times per year and all meetings are held in Lansing. Every CON Commission meeting is open to the public and subject to the Open Meetings Act. Each CON Commission meeting starts with a declaration of conflicts of interests. The Michigan Department of Health and Human Services ("Department") supports the CON Commission and administers the CON program.

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

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

Our review of the program is based on reports provided to the Commission by the Department, which is done at the close of every fiscal year. Copies of FY2017 and FY2018 CON Program Annual Activity Reports are being provided along with this Memo in Attachment B. In addition to these annual reports, the Department provides quarterly program section performance reports to the Commission. These reports demonstrate the effectiveness of the CON program in processing letters of intent, applications, emergency applications, and amendments, as well as issuing decisions within the specified time frames set forth in the Administrative Rules.

We would like to provide the JLC a summary of our activities and accomplishments since the January 2017 report. In the last two years, the Commission has updated 10 of the 15 Review Standards for covered services, including:

- Cardiac Catheterization,
- Hospital Beds,
- Megavoltage Radiation Therapy,
- Open Heart Surgery Services,
- Positron Emission Tomography (PET) Scanners,
- Surgical Services,
- Bone Marrow Transplant Services,
- Heart/Lung and Liver Transplant Services,
- Magnetic Resonance Imaging (MRI), and
- Psychiatric Beds and Services.

In some instances, technical changes were made to modernize standards and/or remove unnecessary regulation. In other instances, major changes were made to benefit the cost, quality and/or access of healthcare for Michigan citizens.

A summary of the changes that have been put into effect or are being proposed to the CON Review Standards during 2017 and 2018 is included in Attachment A.

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

The CON Commission is currently in process seeking recommendations for modifications to three CON review standards. At the time of this report, there is a workgroup reviewing CON Review Standards for Psychiatric Beds and Services, a Standard Advisory Committee is reviewing Megavoltage Radiation Therapy (MRT) Services/Units, and a Standard Advisory Committee is to be seated to review Bone Marrow Transplantation (BMT) Services yet in 2018.

The following review standards will be reviewed in 2019: Air Ambulance Services, Computed Tomography (CT) Scanner Services, Neonatal Intensive Care Services/Beds (NICU), Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups (NH-HLTCU), and Urinary Extracorporeal Shock Wave Lithotripsy Services/Units.

Per our statutory obligation, the CON Commission makes the following recommendations to the Legislature regarding statutory changes to improve the Certificate of Need program; [INSERT RECOMMENDATIONS TO THE LEGISLATURE]
>OR<

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

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

Respectfully yours,

James B. Falahee, Jr, JD, Chairperson

Tom Mittelbrun III, Vice-Chairperson

c: CON Commission
Nick Lyon, Director, MDHHS
Nancy Vreibel, Chief Deputy Director, MDHHS
Matt Lori, Senior Deputy Director of Policy, Planning and Legislative Services, MDHHS
Karla Ruest, Legislative Affairs Director, MDHHS
Joseph Potchen Division Chief, Corporate Oversight Division, Attorney General's Office
Beth Nagel, Planning Office Division Director, MDHHS
Tulika Bhattacharya, Manager, CON Evaluation Section, MDHHS
Brenda Rogers, Special Assistant to the CON Commission, MDHH

SUMMARY OF CON REVIEW STANDARDS REVISIONS FOR CALENDAR YEARS 2017 AND 2018 - ATTACHMENT A

Year	Standard	Commission Plan for Review	Review Process	Summary of Major Changes Made/Proposed
2017	Cardiac Catheterization	Formed a Standard Advisory Committee	Standard Advisory Committee held July - December 2017 CON Commission took Proposed Action at March 27, 2018 meeting Public Hearing Held April 26, 2018 CON Commission took Proposed Action at June 14, 2018 meeting Public Hearing Held July 19,2018 CON Commission took Final Action at September 20, 2018 meeting	• Pacemakers and implantable cardioconverter defibrillators can only be performed in licensed hospitals with diagnostic CC CON approval • Replacement language added • Per physician volumes clarified • Definitions updated throughout
2017	Hospital Beds	Formed a Standard Advisory Committee	Standard Advisory Committee held July - December 2017 CON Commission took Proposed Action at March 27, 2018 meeting Public Hearing Held April 26, 2018 CON Commission took Final Action at June 14, 2018 meeting	• Added Inpatient Rehabilitation Facility Beds Initiation & Replacement requirements • Removed unnecessary regulatory requirements regarding relocating beds • Comparative review requirements modernized • Renewal of lease requirements added
2017	Megavoltage Radiation Therapy	2017: No changes necessary, review in 2020 2018: Formed a Standard Advisory Committee for changes identified	Standard Advisory Committee held June 2018 -	• Volume requirements and procedure weights are being reviewed by the Standard Advisory Committee
2017	Open Heart Surgery Services	Language dependent upon Cardiac Catheterization Standard Advisory Committee	CON Commission took Proposed Action at March 27, 2018 meeting Public Hearing Held April 26, 2018 CON Commission took Proposed Action at June 14, 2018 meeting Public Hearing Held July 19,2018 CON Commission took Final Action at September 20, 2018 meeting	• Adds requirements for replacing an Open Heart Surgery Service
2017	PET Scanners	No changes necessary, review in 2020		
2017	Surgical Services	Department to draft language based on public testimony	CON Commission took Proposed Action at the June 5, 2017 meeting Public Hearing held August 3, 2017 CON Comission took Final Action at September 21, 2017 meeting	• Clarifies requirements for freestanding surgical centers

SUMMARY OF CON REVIEW STANDARDS REVISIONS FOR CALENDAR YEARS 2017 AND 2018 - ATTACHMENT A

Year	Standard	Commission Plan for Review	Review Process	Summary of Major Changes Made/Proposed
2018	Bone Marrow Transplant Services	From a Standard Advisory Committee		• This Standard Advisory Committee is charged to determine if cellular therapies should be considered for regulation under CON or not
2018	Heart/Lung Liver Transplant	No changes necessary, review in 2021		
2018	MRI	No changes necessary, review in 2021		
2018	Psychiatric Beds and Services	From a workgroup		• This workgroups is charged with reviewing the CON methodology for determining inpatient psychiatric bed need and reviewing if there are any appropriate ways to increase flexibility in transfering or creating units with existing child/adolescent and adult beds.

DETAILED CON REVISIONS FOR FY17 AND FY18 – ATTACHMENT B

During FY2017, the CON Commission revised the review standards for Computed Tomography (CT) Services, Magnetic Resonance Imaging (MRI) Services, Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services, Nursing Home and Hospital Long-Term Care Unit (NH-HLTCU) Beds and Addendum for Special Population Groups, and Psychiatric Beds and Services.

CT Services: The revisions to the CON Review Standards for CT Services include the following and became effective on December 9, 2016.

- Section 2: Definitions removed and/or updated, and the following definition has been modified as shown:
    - "CT scanner" means x-ray CT scanning systems capable of performing CT scans of the head, other body parts, or full body patient procedures including Positron Emission Tomography (PET)/CT scanner hybrids if used for CT only procedures. The term does not include emission computed tomographic systems utilizing internally administered single photon gamma ray emitters, positron annihilation CT systems, magnetic resonance, ultrasound computed tomographic systems, CT simulators used solely for treatment planning purposes in conjunction with an MRT unit, and non-diagnostic, intra-operative guidance tomographic units, AND DENTAL CT SCANNERS THAT generate a peak power of 5 kilowatts or less as certified by the manufacturer AND ARE specifically designed to generate CT images to facilitate dental procedures BY A LICENSED DENTIST UNDER THE PRACTICE OF DENTISTRY. Definitions removed and updated to de-regulate dental CT scanners used by dentists in the practice of dentistry. This is intended to provide better access to the consumer and more flexibility to the provider in their practice as well as decrease costs.
- Section 3: Removed reference to dental CT as it's no longer.
- Old Section 4: Removed as it's no longer needed.
- New Section 4: Removed reference to dental CT as it's no longer needed.
- Old Section 6: Removed as it's no longer needed.
- New Section 5: Removed reference to dental CT as it's no longer needed.
- New Section 5(2): The 36-month in operation requirement is waived if one of the following has been met. Reduced regulation allows for facilities to more easily replace an existing fixed CT scanner service to a new location in certain situations that are unforeseen to the applicant (same as MRI language), which is intended to decrease costs and increase quality while maintaining access.
    - (ii) THE OWNER OF THE BUILDING WHERE THE SITE IS LOCATED HAS INCURRED A FILING FOR BANKRUPTCY UNDER CHAPTER SEVEN (7) WITHIN THE LAST THREE YEARS;
    - (iii) THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL;

    Removed volume requirements for replacement of an existing fixed CT service and its unit(s) to a new site in certain situations that are unforeseen to the applicant (same as MRI language), which is intended to decrease costs and increase quality while maintaining access:

    - (ii) THE OWNER OF THE BUILDING WHERE THE SITE IS LOCATED HAS INCURRED A FILING FOR BANKRUPTCY UNDER CHAPTER SEVEN (7)

WITHIN THE LAST THREE YEARS;
  - (iii) THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL; OR
  - (iv) THE CT SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF AN ENTIRE HOSPITAL TO A NEW GEOGRAPHIC SITE AND HAS ONLY ONE (1) CT UNIT.
- Old Section 8: Removed as it's no longer needed if dental CT scanners are de-regulated.
- New Section 6: Modified to allow for the acquisition of a fixed or mobile CT scanner service not meeting volume requirements by an entity if the CT scanner service is 1) owned by the applicant, 2) is under common control by the applicant, or 3) has a common parent as the applicant. The acquisition of a CT scanner service does not change the location of the service. The service would have to meet all other applicable CT standards and project delivery requirements. Reduced regulation allows for facilities to more easily realign their assets when part of a larger health system (same as MRI language), which is intended to decrease costs while maintaining access.
- Old Section 10: Removed as it's no longer needed.
- Old Section 12: Removed as it's no longer needed.
- Old Section 17: Removed as it's no longer needed.
- New Section 14(2)(c): Modified - Through the CON Annual Survey, freestanding facilities are stating that they can't meet this because they are not open 24 hours. This is a requirement that goes back to the 1980's and the Planning Policies. At the time, only hospitals were eligible to provide CT services. Freestanding facilities were added in 1990, and this requirement was maintained. Striking "on a 24-hour basis," still ensures that there is a physician available to make the final interpretation and makes it easier for all facilities to comply with making it more of a technical edit for clarity.
- New Section 14(2)(f): Through the CON Annual Survey, freestanding facilities are stating that they can't meet this because they are not open 24 hours. Again, this is a requirement that goes back to the 1980's and the Planning Policies. At the time, only hospitals were eligible to provide CT services. Freestanding facilities were added in 1990, and this requirement was maintained. This is a technical clarification ensuring that the appropriate facilities are complying with the requirement.
- Old Section 20(5) & (6): Removed as it's no longer needed.
- New Section 16: Removed reference to dental CT as it's no longer needed.
- Old Section 23(2): Removed as it's no longer needed.
- New Section 17(2): Removed reference to dental CT as it's no longer needed.
- Other technical edits.

MRI Services: The revisions to the CON Review Standards for MRI Services include the following and became effective on October 21, 2016:

- Section 6 has been modified to allow for the acquisition of a fixed or mobile MRI service not meeting volume requirements by an entity if the MRI service is 1) owned by the applicant, 2) is under common control by the applicant, or 3) has a common parent as the applicant. The acquisition of an MRI service does not change the location of the service. The service would have to meet all other applicable MRI standards and project delivery requirements. Reduced regulation allows for facilities to more easily realign their assets when part of a larger health system, which is intended to decrease costs while maintaining access and quality.

- Other technical edits.

The revisions to the CON Review Standards for NICU and Special Newborn Nursing Services include the following and have been implemented:

- Section 2(1)(v): Definition for "special care nursery services" or "SCN services" has been modified for clarity and what types of services are provided in SCNs. This is a technical edit that does not make any programmatic changes in CON regulation.
- Section 2(1)(w): Added a definition for "well newborn nursery services" and clarifying that well newborn nurseries do not require a CON. This is a technical edit that does not make any programmatic changes in CON regulation.
    - (w) "WELL NEWBORN NURSERY SERVICES" MEANS PROVIDING THE FOLLOWING SERVICES AND DOES NOT REQUIRE A CERTIFICATE OF NEED:
      (i) THE CAPABILITY TO PERFORM NEONATAL RESUSCITATION AT EVERY DELIVERY;

      (ii) EVALUATE AND PROVIDE POSTNATAL CARE FOR STABLE TERM NEWBORN INFANTS;

      (iii) STABILIZE AND PROVIDE CARE FOR INFANTS BORN AT 35 TO 37 WEEKS' GESTATION WHO REMAIN PHYSIOLOGICALLY STABLE; AND

      (iv) STABILIZE NEWBORN INFANTS WHO ARE ILL AND THOSE BORN LESS THAN 35 WEEKS OF GESTATION UNTIL THEY CAN BE TRANSFERRED TO A HIGHER LEVEL OF CARE FACILITY.
- Section 7(2)(c): Eliminated the language that limits the expansion of beds to no more than five. The current standard limits the expansion to no more than 5 beds even if the methodology calculation is higher. There is no need for this cap.
- Other technical edits.

Psychiatric Beds and Services: The revisions to the CON Review Standards for Psychiatric Beds and Services include the following and became effective on December 9, 2016:

- Section 2: Definition has been modified as follows:
    - "Comparative group" means the applications which have been grouped for the same type of project in the same planning area OR STATEWIDE SPECIAL POPULATION GROUP and are being reviewed comparatively in accordance with the CON rules. Definition updated to include special population groups covered under the new addendum, which is intended to provide additional access.
- Section 15(1)(d): Modified as follows:
    - There shall be the following minimum staff employed either on a full-time basis or ACCESS TO on a consulting basis AS NEEDED. This will provide more flexibility to the provider, which is intended to positively impact patient access.
- Addendum for Special Population Groups is being added for specific needs, i.e., developmentally disabled, geriatrics, and medical psychiatric. This will provide more access to beds for these specific hard to place patients.
- Other technical edits.

DETAILED CON REVISIONS FOR FY17 AND FY18 – ATTACHMENT B

Nursing Home- Hospital Long Term Care Unit Beds: The revisions to the CON Review Standards for NH-HLTCU Beds and Addendum for Special Population Groups include the following and became effective on September 21, 2017:

- Updated the Department name throughout the document.
- Section 2(1)(b): The Average Daily Census (ADC) adjustment factor definition was updated to apply a factor of 0.90 for all planning areas to reflect the overall change in occupancy and lengths of stay.
- Information contained in Appendix B will be moved to the Department website as opposed to being imbedded in the standard.
- Section 6: The high occupancy provisions were revised to be facility specific, not county, based on the current environment of shorter lengths of stay and managed care.
- Section 9: Language was added that clarifies requirements for a new entity with no prior NH-HLTCU history that is applying to acquire a NH-HLTCU.
- Section 10: The criteria for a Bariatric patient room has been updated and clarified.
- Section 14: Language was added to clarify that nursing home replacement will not be subject to comparative review if the new site is within the same planning area as the existing site. Reduced regulation provides facilities more opportunities for submitting an application versus the current three times a year.
- Appendices C and E were removed as they are no longer needed due to other changes in the standards.
- In the statewide pool for the needs of special population groups addendum, the requirements to initiate hospice beds were removed as they are no longer needed, and requirements to initiate and acquire Bariatric patient beds were added along with corresponding project delivery requirements as there is an increased need for this special population group.
- The method for adjusting and redistributing the number of beds available in the statewide pool for the needs of special population groups was revised.
- Other technical edits.

During FY2018, the CON Commission revised the review standards for Surgical Services and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services.

Surgical Services: The revisions to the CON Review Standards for Surgical Services include the following and became effective on November 17, 2017:

- Updated the Department name throughout the document.
- Section 4(3)(a): Added language regarding commitment letters and the use of historical surgical cases for initiation.
- Section 11(2)(e): Added new language regarding commitment letters and the use of historical surgical cases for initiation as shown below. Less regulation will ease the process for the applicant when using its own data to initiate:
    - (e) SUBSECTION 11(2)(d) SHALL NOT APPLY IF THE PROPOSED PROJECT INVOLVES THE INITIATION OF A SURGICAL SERVICE AT A NEW FSOF OR A NEW ASC AT A NEW GEOGRAPHICAL SITE UTILIZING THE HISTORICAL SURGICAL CASES OF THE APPLICANT AND THE NEW SERVICE IS OWNED BY THE SAME APPLICANT. THE APPLICANT FACILITY COMMITTING SURGICAL DATA HAS COMPLETED THE DEPARTMENTAL FORM THAT CERTIFIES THE SURGICAL CASES WERE PERFORMED AT THE COMMITTING FACILITY AND THE SURGICAL CASES WILL BE

TRANSFERRED TO THE PROPOSED SURGICAL FACILITY FOR NO LESS THAN 3 YEARS SUBSEQUENT TO THE INITIATION OF THE SURGICAL SERVICE PROPOSED BY THE APPLICANT.

- Other technical edits.

Urinary Extracorporeal Shock Wave Lithotripsy: The revisions to the CON Review Standards for UESWL Services include the following and became effective on March 29, 2018:

- Updated the Department name throughout the document.
- Section 3(1)(c)(iii) and (vii): FSOF and ASC sites can't typically meet these requirements. The change is for administrative feasibility. (Note: The option for a contractual agreement was removed in 1998.)
    - EITHER 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.
    - EITHER on-site OR THROUGH A CONTRACTUAL AGREEMENT WITH ANOTHER HEALTH FACILITY, A 23-hour holding unit.
- Section 3(2): Added requirements to convert from mobile to fixed UESWL services. The change is consistent with other CON covered mobile modalities that offer conversion and is meant to increase access and decrease costs.
    - (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 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(2): Removed the volume requirement for replacement. This is similar to other CON covered clinical services.
- Section 4(3): Modified as follows. This will still allow for conversion from fixed to mobile, but the service will have to demonstrate compliance with the volume requirement. If a host site was converted to a fixed unit for better access to UESWL services at that site, then converting it back to a mobile unit seems to defeat that purpose. This language was originally written to convert fixed units to mobile.
  (3) An applicant PROPOSING TO REPLACE 1 existing fixed UESWL unit with 1 mobile UESWL unit SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF 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.

- Section 4(4): The 36-month in operation requirement is waived if one of the following has been met. Reduced regulation allows for facilities to more easily replace an existing fixed UESWL service to a new location in certain situations that are unforeseen to the applicant (same as MRI and CT language).
    - (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;

  Removed volume requirements for replacement of an existing fixed UESWL service and its unit(s) to a new site in certain situations that are unforeseen to the applicant (same as MRI and CT language):
    - (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.
- Section 6 has been modified to allow for the acquisition of a fixed or mobile UESWL service not meeting volume requirements by an entity if the UESWL service is 1) owned by the applicant, 2) is under common control by the applicant, or 3) has a common parent as the applicant. The acquisition of an UESWL service does not change the location of the service. The service would have to meet all other applicable UESWL standards and project delivery requirements. Reduced regulation allows for facilities to more easily realign their assets when part of a larger health system.
- Section 7(4) has been removed. This will give mobile routes more flexibility to change the route to accommodate changes that may be caused by facilities converting to a fixed unit.
- Appendix A: The factor for calculating projected UESWL procedures has been updated.
- Other technical edits.

The following review standards were reviewed with an anticipated completion in FY2019:

Hospital Beds: Proposed action was taken by the Commission at its March 27, 2018 meeting. The standards were submitted to the joint legislative committee (JLC) and a Public Hearing was held. The Commission took final action at its June 14, 2018 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period. Standards will become effective in FY2019.

Cardiac Catheterization Services: Proposed action was taken by the Commission at its June 14, 2018 meeting. The standards were submitted to the joint legislative committee (JLC) and a Public Hearing was held. The Commission took final action at its September 20, 2018 Commission meeting and were submitted to the JLC and Governor for the required 45-day

review period. Standards will become effective in FY2019.

Open Heart Surgery Services: Proposed action was taken by the Commission at its June 14, 2018 meeting. The standards were submitted to the joint legislative committee (JLC) and a Public Hearing was held. The Commission took final action at its September 20, 2018 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period. Standards will become effective in FY2019.

STATUS REPORT FROM THE MRT SAC

To: CON Commission
From: Brian Kastner, MD
MRT SAC Chair
Date: September 20, 2018 CON Commission meeting
RE: MRT SAC update

The MRT SAC has met three times thus far: June 28, July 26 and August 30, 2018. The CON gave two charges to the SAC to consider: treatment weightings and volume requirements. The SAC reviewed both at the first meeting. The SAC discussed the changing practice patterns that have contributed to lower utilization. In particular, the SAC noted that the trend toward delivering care in fewer treatment fractions (hypo-fractionation) has lowered the logistical and financial burden on patients and payers. However, delivery of hypo-fractionated care, while benefiting patients and payers, is lowering MRT unit utilization numbers and subjecting centers to compliance scrutiny due to failure to meet minimum volumes. The SAC concluded that the change in practice patterns merited a thorough review of treatment weightings and volume requirements.

The SAC approached the question of treatment weightings by first agreeing that weightings should reflect MRT utilization time. Secondly, we conducted a survey to solicit the standard or average time required to deliver treatments. Thereafter, the SAC revised the weightings to reflect the results of this survey. (attached). The SAC agreed to maintain a 15-minute base unit for the equivalent treatment visit (ETV) to both preserve consistency with previous standards and to simplify evaluation of the impact of any subsequently proposed volume standards.

The SAC began its review of the current volume requirements with the recognition that, for every one thousand ETVs, the MRT unit was operating one hour per day throughout the year. In consideration of the Minimum volume, we observed that the current 8000 ETV minimum assumed 8-hour-per-day operation, and we felt this to be an unreasonably high minimum volume. After thorough discussion of cost, quality and access, we agreed that any unit delivering at least 4000 ETV per year should not be subject to regulatory sanction.

At subsequent meeting(s), we will consider volume requirements for MRT replacement, initiation and expansion.

Interim Report
Psychiatric Beds and Services Workgroup Meeting
18 September 2018
Prepared by Laura Hirshbein, MD, PhD

Since its approval, the Psychiatric Beds and Services Workgroup has met once, on 16 August 2018. More than 30 people from all over the state gathered to discuss a plan to address the eight specific charges from the Certificate of Need Chairperson. We began with a brief review of the history of the Certificate of Need Commission and its process for work. We also reviewed the process that we will follow for this workgroup.

We had a robust discussion of the first charge, to consider modifying the definition of "Mental Health Professional" in the formal CoN standards to include advanced practice providers (APPs, physician assistants and/or nurse practitioners). While there was general consensus that APPs could perform valuable service to the state in terms of addressing mental health access, we had concerns that there was confusion across multiple different regulatory processes in the state for APPs. It was noted that the Mental Health Code does not permit APPs to function in the same role as physicians (with some possible confusion about a difference between PAs and NPs in this regard). The CoN standards cannot supersede the Mental Health Code. **We would therefore recommend that the standards regarding APPs be clarified throughout the state and that the CoN language be modified to comply with the broader standard.**

We then began to discuss a strategy for addressing charge 3, to review the methodology to determine inpatient need in the state. There was consensus that most of the other charges would flow from the work we did on charge 3 and so this was the next logical item to address. We reviewed the data provided by MDHHS on the number of licensed psychiatric beds in the state and the relative rate of occupancy. According to the data provided, there should be adequate psychiatric beds in Michigan. We agreed, however, that the clinical experience of community mental health organizations and emergency departments did not match the data we were given.

We agreed that we were going to attempt to gather more data before our next meeting, which is scheduled for 17 October 2018. One volunteer was going to reach out to the Association of Behavioral Health Care to ask members about potential differences between operational bed availability and licensed bed availability. Another was going to survey CMHs in the state to find out about wait times and bed access issues. Some of our payor colleagues were also going to give us an indication of how far people were having to go to find available psychiatric beds. MDHHS staff were going to share information from a survey done a few years ago about reasons for denials of admission from emergency departments.

Agenda for next meeting:

- Presentation by Paul Delamater, a consultant currently on faculty at UNC, on the methodology behind psychiatric Certificate of Need determinations.
- Discussion of additional data:

- Estimation of operational bed availability (versus licensed bed availability) in the state.
- Experience of CMHs and prepaid inpatient health plans.
- Exploration of reasons for low occupancy in some areas (coupled with widespread perception that there are not enough beds).
- Special bed shortage areas for children/adolescents, developmentally disabled individuals, patients with medical issues and elderly patients.

CERTIFICATE OF NEED

3rd 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	3rd Quarter	Year-to-Date
Approved projects requiring 1-year follow up	63	216
Approved projects contacted on or before anniversary date	47	158
Approved projects completed on or before 1-year follow up	75%	
CON approvals expired	52	91
Total follow up correspondence sent	174	574
Total approved projects still ongoing	299	

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

- The Department is in the process of conducting statewide compliance reviews for Neonatal Intensive Care Unit (NICU) beds, Special Care Nursery (SCN) services, Urinary Extra Corporeal Shock Wave Lithotripsy (UESWL) services, Open Heart Surgery (OHS) services and Computed Tomography (CT) (currently on hold) services utilizing 2016 CON Annual Survey data. The Department is in the process of finalizing the evaluated annual survey data, review standard requirements, and CON approved facilities for these selected services and has identified the facilities for compliance investigations. The Department is in the process of setting up conference calls with these identified facilities to discuss compliance issues. The finding of the statewide compliance reviews will be reported to the CON Commission at a later date.

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

CERTIFICATE OF NEED

3rd 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	3rd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	119	N/A	283	N/A
Letters of Intent Processed within 15 days	119	100%	282	99%
Letters of Intent Processed Online	119	100%	283	100%

Administrative Rule R325.9201 requires the Department to request additional information from an applicant within 15 days upon receipt of an application, if additional information is needed.

Activity	3rd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	90	N/A	234	N/A
Applications Processed within 15 Days	89	99%	233	99%
Applications Incomplete/More Information Needed	69	77%	170	73%
Applications Filed Online*	82	100%	217	100%
Application Fees Received Online*	12	15%	44	20%

* Number/percent is for only those applications eligible to be filed online, potential comparative and comparative applications are not eligible to be filed online, and emergency applications have no fee.

Administrative rules R325.9206 and R325.9207 require the Department to issue a proposed decision for completed applications within 45 days for nonsubstantive, 120 days for substantive, and 150 days for comparative reviews.

Activity	3rd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	40	100%	142	100%
Substantive Applications	18	100%	66	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	3rd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Emergency Applications Received	0	N/A	0	N/A
Decisions Issued within 10 workings Days	0	N/A	0	N/A

Administrative Rule R325.9413 requires the Department to process amendment requests within the same review period as the original application.

Activity	3rd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	24	100%	62	100%

Section 22231(10) of the Public Health Code requires the Department to issue a refund of the application fee, upon written request, if the Director exceeds the time set forth in this section for a final decision for other than good cause as determined by the Commission.

Activity	3rd Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	3rd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	79	N/A	175	N/A
FOIA Requests Processed on Time *	79	100%	175	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: CON Evaluation Section, Michigan Department of Health and Human Services.

STATE OF MICHIGAN
DEPARTMENT OF ATTORNEY GENERAL

BILL SCHUETTE
ATTORNEY GENERAL

MEMORANDUM

September 13, 2018

TO: James Falahee
CON Commission Chair

FROM: Carl Hammaker CJH
Assistant Attorney General
Corporate Oversight Division

RE: Legal Report for the September 20, 2018 Commission Meeting

We currently have one pending case in the Michigan Administrative Hearing System. On July 10, 2018, the Department issued its decision to expire CON 13-0375. CON 13-0375 was an approved project to make a change to the bed capacity at the Hickory Ridge of Temperance facility by adding 20 nursing home beds into a newly constructed addition. The Department expired the CON for lack of progress following the expiration of the second construction extension. Hickory Ridge appealed the Department's decision. The matter is set for a status conference with the Administrative Law Judge on October 18, 2018.

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

CJH
Cc: Elizabeth Nagel
Joseph Potchen

american Surgical Centers II

Specializing in High Quality Patient Care Since 2001

7091 Orchard Lake Road Suite 230 West Bloomfield, MI 48322
Phone: 248-538-7095 Fax: 248-538-7298

July 17, 2018

Attn: CON Commission
South Grand Building, 5th Floor
333 S. Grand Avenue, P.O. Box 30195
Lansing, MI 48909

RE: PACEMAKER AND ICD PLACEMENT IN AMBULATORY SURGERY CENTER (ASC) SETTING

To Whom It May Concern:

This testimony serves as a request for CON Commission members to consider allowing Permanent Pacemakers and Internal Cardiac Defibrillator (ICD) implant placement to be performed in an ambulatory surgery center (ASC) setting. The Commission shall consider unbundling the following minimally invasive procedures from Therapeutic Cardiac Catherization Services category, making them permittable under Surgical Services:

- PERMANENT PACEMAKER IMPLANTATION, (placement only)
- ICD IMPLANTATION (SUBCUTANEOUS) (placement only)

American Surgical Centers II, LLC is a Medicare certified and AAAHC accredited ASC with a desire to perform the above stated minimally-invasive procedures. This ASC would like to propose and spearhead a pilot program where, with state's oversight and permission, the procedures above are performed to reflect an outcome no less safe than when performed in a catherization lab or a hospital OR setting. American Surgical Centers II, LLC successfully renewed its 3-year CMS certification in January of 2018, a 3-year AAAHC accreditation in November of 2017, and a successful annual state survey in May 2018. As you may know, CMS and AAAHC mandate their facilities adhere to the highest standards of quality and patient care. A few standards include:

- Transfer agreement- written transfer agreement with a nearby hospital (3.5 mi distance) along with a protocol for immediate transfer.

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- Multiple emergency personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation available whenever there is a patient in the ASC. All ACLS-trained nursing staff onsite.
- We credentialed a Board-certified interventional cardiologist to oversee pacemaker and ICD placement units. American Surgical Centers has qualified physicians and a qualified anesthesia team onboard.
- Consistent measuring, analyzing, and tracking of quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.
- Safe and sanitary environment of care monitored by Safety and Professional Standard Committee
- Infection Control Program aiming to prevent, identify, and manage infections, monitored by a properly trained Infection Control Officer/RN serving as Director of Nursing. American Surgical Centers holds a record of zero incidents of infection in its 20 years of operation.
- Emergency preparedness-emergency plans, policies and procedures, consistent annual and quarterly training and testing. Successful passing of annual fire inspection in January 2018.

Lower Cost and Benefits:

As you may know, CMS approves pacemakers and ICDs to be performed in an ASC setting and many ASCs in other states are performing such procedures successfully. Regarding cost comparison, an important benefit to the patient will be the option to have this performed at a lower-cost ambulatory surgery center as oppose to a hospital.

CPT	Short Descriptor	MC ASC	MC HOPD
33206	Insert heart pm atrial	$7,778.45	$9,747.32
33207	Insert heart pm ventricular	$7,831.96	$9,747.32
33208	Insrt heart pm atrial & vent	$8,010.02	$9,747.32
33224	Insert pacing lead & connect	$7,869.28	$9,747.32
33226	Reposition l ventric lead	$1,298.71	$2,492.57
33249	Insj/rplcmt defib w/lead(s)	$27,339.22	$30,959.99

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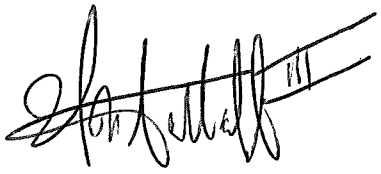
We request that CON Commission further review the capability of properly equipped and certified ambulatory surgery centers to perform such procedures in a safe manner and propose a regulatory change. As stated above, our facility is CMS certified and AAAHC accredited, as well as equipped with cardiac and defibrillator management in both peri-operative and operating room suite to lend support to our interventional cardiologist.

In case a regulatory change is not possible, American Surgical Centers would request that CON Commission consider our offer for a pilot project that could play a role in future decisions. Feel free to contact us if you would like more information or to further discuss this matter.

Thank you for the opportunity to provide comments on CON Review Standards for Cardiac Catherization Services.

Sincerely,



Management Team
American Surgical Centers II
7091 Orchard Lake Road Ste 230
West Bloomfield, MI 483222
Phone: 586-636-4090
Fax: 586-498-9460

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.

CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

Attachment M

	2018											
	Jan	Feb	March	April	May	June	July	August	September	October	November	December
Commission Meetings		Special Meeting	Meeting			Meeting			Meeting			Meeting
Air Ambulance Services										Public Comment Period		
Bone Marrow Transplantation (BMT) Services		Discussion	Draft Language Presented				SAC Nomination & Selection Period					
Cardiac Catheterization Services			Report/Draft Language Presented/ Proposed Action	Public Hearing		Report/ Proposed Action	Public Hearing		Report/ Final Action			
Computed Tomography (CT) Scanner Services										Public Comment Period		
Hospital Beds			Report/Draft Language Presented/ Proposed Action	Public Hearing		Report/ Final Action						
Megavoltage Radiation Therapy (MRT) Services/Units		Discussion/ Report; SAC Nomination & Selection Period starts	SAC Nomination & Selection Period			SAC Meeting	SAC Meeting	SAC Meeting		SAC Meeting	SAC Meetings	SAC Meeting
Neonatal Intensive Care Services/Beds (NICU)										Public Comment Period		
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups										Public Comment Period		
Open Heart Surgery (OHS)			Report/ Draft Language Presented/ Proposed Action	Public Hearing		Report/ Proposed Action	Public Hearing		Report/ Final Action			

Attachment M

	2018											
	Jan	Feb	March	April	May	June	July	August	September	October	November	December
Psychiatric Beds and Services		Discussion; SAC Nomination & Selection Period starts	SAC Nomination & Selection Period				Workgroup Meeting	Workgroup Meeting	Workgroup Meeting	Workgroup Meeting	Workgroup Meeting	Workgroup Meeting
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units										Public Comment Period		
New Medical Technology Standing Committee	Department Monitoring					Department Monitoring				Department Monitoring		
2-year Report to Joint Legislative Committee (JLC) – 1/1/19									Review Draft Report			Approve Report
FY2018 CON Annual Report												Present Report to Commission

For Approval September 20, 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	2021
Surgical Services	November 17, 2017	2020
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	May 29, 2018	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.