TENTATIVE AGENDA

CERTIFICATE OF NEED(CON) COMMISSION CARDIAC CATHETERIZATION SERVICES STANDARD ADVISORY COMMITTEE (CCSAC) MEETING

Thursday, July 13, 2017
9:30 a.m. – 11:30 p.m.
South Grand Building
333 S. Grand Ave,
1st Floor, Grand Conference Room
Lansing, MI 48933

Agenda Items

I.	Call to Order	Chairperson, Shukri David
II.	Introduction of Members and Staff	Chairperson, Shukri David
III.	Declaration of Conflicts of Interests	Chairperson, Shukri David
IV.	Review of Agenda	Chairperson, Shukri David
V.	Basic CON Overview	Beth Nagel, MDHHS
VI.	Review and Discussion of Charge	Chairperson, Shukri David
VII.	Next Steps	Chairperson, Shukri David
VIII.	Future Meeting Dates – August 14, 2017; September 14, 2017; October 19, 2017; November 9, 2017; & December 20, 2017	
IX.	Public Comment	
X.	Adjournment	

NOTE: There will be a 10-15 minute break at approximately 11:00 a.m.

Be sure all cellular telephones and pagers are turned off or set to vibrate during meeting.

NOTES: 1) *To be included as part of the official record, the SAC would appreciate brief and concise written copies of the oral testimony and/or other documentation/data pertaining to Public Comment items.*

2) *Handouts available for the public will be limited to the final agenda.*

3) *Public Comment for all items will be limited to three (3) minutes per item per speaker per organization with a maximum of ten (10) minutes if speaking on four (4) or more items. This time may be adjusted dependent upon the number of speakers.*

EXCERPT FROM CON COMMISSION BYLAWS
ARTICLE IX – CONFLICT OF INTEREST PROVISIONS

B. Definition - Conflict of Interest

1. Under the State Ethics Act, 1973 PA 196, MCL 15.341, et seq, and in accordance with the Advisory Opinion of the State Board of Ethics of November 5, 2004, a conflict of interest for Commission members exists when the individual member has a financial or personal interest in a matter under consideration by the Commission. The personal interest of a Commission member includes the interest of the member's employer, even though the member may not receive monetary or pecuniary remuneration as a result of an adopted CON review standard.

2. A Commission member does not violate the State Ethics Act if the member abstains from deliberating and voting upon the matter in which the member's personal interest is involved.

3. A Commission member may deliberate and vote on matters of general applicability that do not exclusively benefit certain health care facilities or providers who employ the Commission member, even if the matter involves the member's employer or those for whom the member's employer does work.

4. Deliberating includes all discussions of the pertinent subject matter, even before a motion being made.

C. Procedures - Conflict of Interest

1. A Commission member must disclose any potential conflict of interest after the start of a meeting, when the Commission begins to consider a substantive matter, or, where consideration has already commenced, when a conflict or potential conflict of interest becomes apparent to the member.

2. After a meeting is called to order and the agenda reviewed, the chairperson must inquire whether any Commission member has a conflict or potential conflict of interest with regard to any matters on the agenda.

3. A Commission member who is disqualified from deliberating and voting on a matter under consideration due to a conflict of interest may not be counted to establish a quorum regarding that particular matter.

4. Where a Commission member has not discerned any conflict of interest, any other Commission member may raise a concern whether another member has a conflict of interest on a matter. If a second member joins in the concern, the Commission must discuss and vote on whether the member has a conflict of interest before continuing discussion or taking any action on the matter under consideration. The question of conflict of interest is settled by an affirmative vote of a majority of those Commission members appointed and serving, excluding the member or members in question.

5. The minutes of the meeting must reflect when a conflict of interest had been determined and that an abstention from deliberation and voting had occurred.

Michigan Certificate of Need

CARDIAC CATHETERIZATION STANDARD ADVISORY COMMITTEE

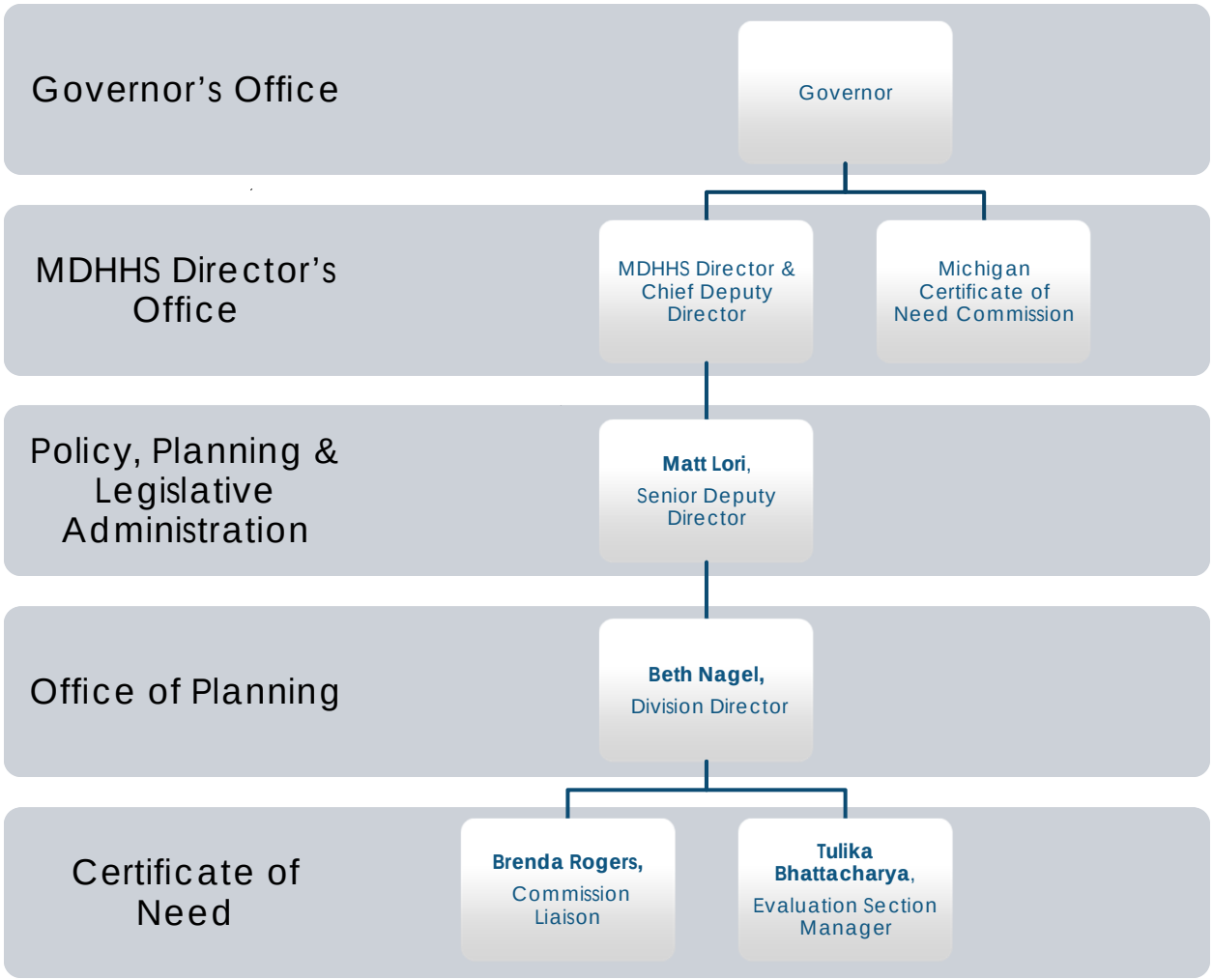
JULY 13, 2017

What is Certificate of Need?

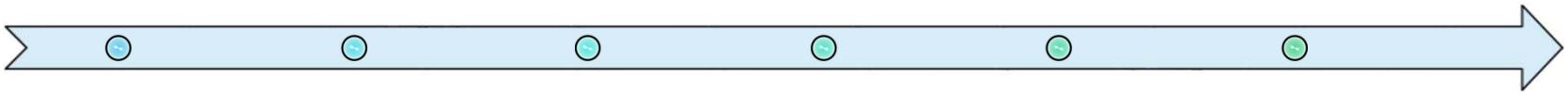
- A health service & equipment regulatory program
- Created by state law
- Intended to balance cost, quality and access by ensuring that only needed health services are developed in Michigan
- Administered by the Michigan Department of Health and Human Services
- Governor-appointed Commission develops and updates standards

MDHHS
Michigan Department of Health & Human Services

Organization



Michigan Certificate of Need History



1974	1978	1986	1988	2002	2017
Federal Mandate: All states have to develop a CON program	Michigan's CON Program is put into state law	Federal Mandate Rescinded: 38 of 50 states keep CON program	Michigan's First Legislative Reform of CON	Michigan's Second Legislative Reform of CON	Today: Focus on quality standards

MDHHS
Michigan Department of Health & Human Services

What is Certificate of Need?

- A healthcare provider must apply for a Certificate of Need in order to operate one of the 15 covered clinical services

CON Covered Clinical Services	
Air Ambulance Services (helicopters only)	Cardiac Catheterization Services
Computed Tomography (CT) Scanners	Hospital Beds
Magnetic Resonance Imaging (MRI)	Megavoltage Radiation Therapy (MRT)
Neonatal Intensive Care Units (NICU)	Nursing Home Beds
Open Heart Surgery Services	Positron Emission Tomography (PET) Scanners
Psychiatric Beds (Acute Inpatient)	Surgical Services
Transplant Services: Bone Marrow, Heart, Lung & Liver	Urinary Lithotripter Services

MDHHS
Michigan Department of Health & Human Services

Obtaining a Certificate of Need

- In order to be approved for a Certificate of Need in Michigan a provider must:
  - Meet Michigan CON criteria outlined in the corresponding CON standard
  - Demonstrate “need” per the corresponding CON Standard
  - Agree to specific project delivery requirements
  - Agree to meet specific service volumes
  - Provide data to MDHHS regularly for the life of the service
  - Apply for another CON before specific changes are made to the service (relocation, replacement, acquisition, for example)
  - Understand that a CON can be revoked

MDHHS
Michigan Department of Health & Human Services

The Certificate of Need Standards

- Created and updated by CON Commission
- Must be updated at least every three years
- Are prospective (not retroactive)
- Contain specific requirements to initiate, replace, acquire, relocate (as necessary)
- Contain Project Delivery Requirements

MDHHS
Michigan Department of Health & Human Services

How a Standard Forms

Public Comment Period

- Every CON Standard must be updated every three years. Each year, a public hearing is held to get solicit input on changes, updates, issues, etc. for 1/3 of the standards

Commission Special Meeting

- Every January the CON Commission holds a special meeting to determine how each standard will be updated. The options are:

1) No updates necessary

2) Deregulate

3)Continue regulation with modifications to the standard

Commission Options for Updating

- To continue regulation and made updates, then the following options are explored:

1) Commission makes changes

2) Department drafts changes

3) A Workgroup makes recommend-ations

4) A SAC makes recommend-ations

MDHHS
Michigan Department of Health & Human Services

Standard Advisory Committees

- Deliver recommendations to the CON Commission based on a specific "Charge"
- Composition outlined in statute
  - Made up of 2/3 of subject matter experts
  - Must representatives of 1 each of consumers; providers; payers and purchasers
- Must complete work within 6 months of first meeting date
- All meetings open to the public and comply with Michigan Open Meetings Act
  - If a quorum of the SAC members is present at any gathering, this becomes a public meeting

MDHHS
Michigan Department of Health & Human Services

CARDIAC CATHETERIZATION SERVICES
STANDARD ADVISORY COMMITTEE (SAC) APPROVED CHARGE
Approved by the CON Commission on January 26, 2017

At a minimum, the Cardiac Catheterization Services SAC should consider reviewing and recommending any necessary changes to the Cardiac Catheterization Services Standards regarding the following:

1. Determine if modifications are necessary to section 10(5)(f), specifically whether or not this section should apply only to facilities that do not have on-site open heart surgery (OHS).

2. Determine if pacemakers and implantable cardioverter defibrillator (ICD) implants should be allowed to be performed in ambulatory surgical centers (ASCs) or only in licensed hospitals.

3. Consider the following definitions and determine if revisions are necessary: Primary Percutaneous Coronary Intervention (PCI); diagnostic cardiac catheterization service; elective PCI services without on-site OHS; therapeutic cardiac catheterization service and electrophysiology study.

4. Review section 10(5)(c) to determine if it is appropriate to exclude patients with cardiogenic shock.

5. Review section 11 to determine if it is appropriate to incorporate additional interventional procedures that are performed in a cardiac catheterization laboratory but are not currently identified or weighted in section 11.

6. Consider revisions to clarify section 4(13)(a) and (b).

7. Consider requirements for replacing a cardiac catheterization service from one existing licensed hospital to another existing licensed hospital.

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

Where did the Charge come from?

- Public Comment Period in October
  - Acceptance of written comments/testimony by MDHHS on behalf of the Commission
  - Commission members and MDHHS staff review all of the comments/testimony received
  - Recommendations offered to the Commission by the Department
- CON Commission develops and approves the final charge to the SAC

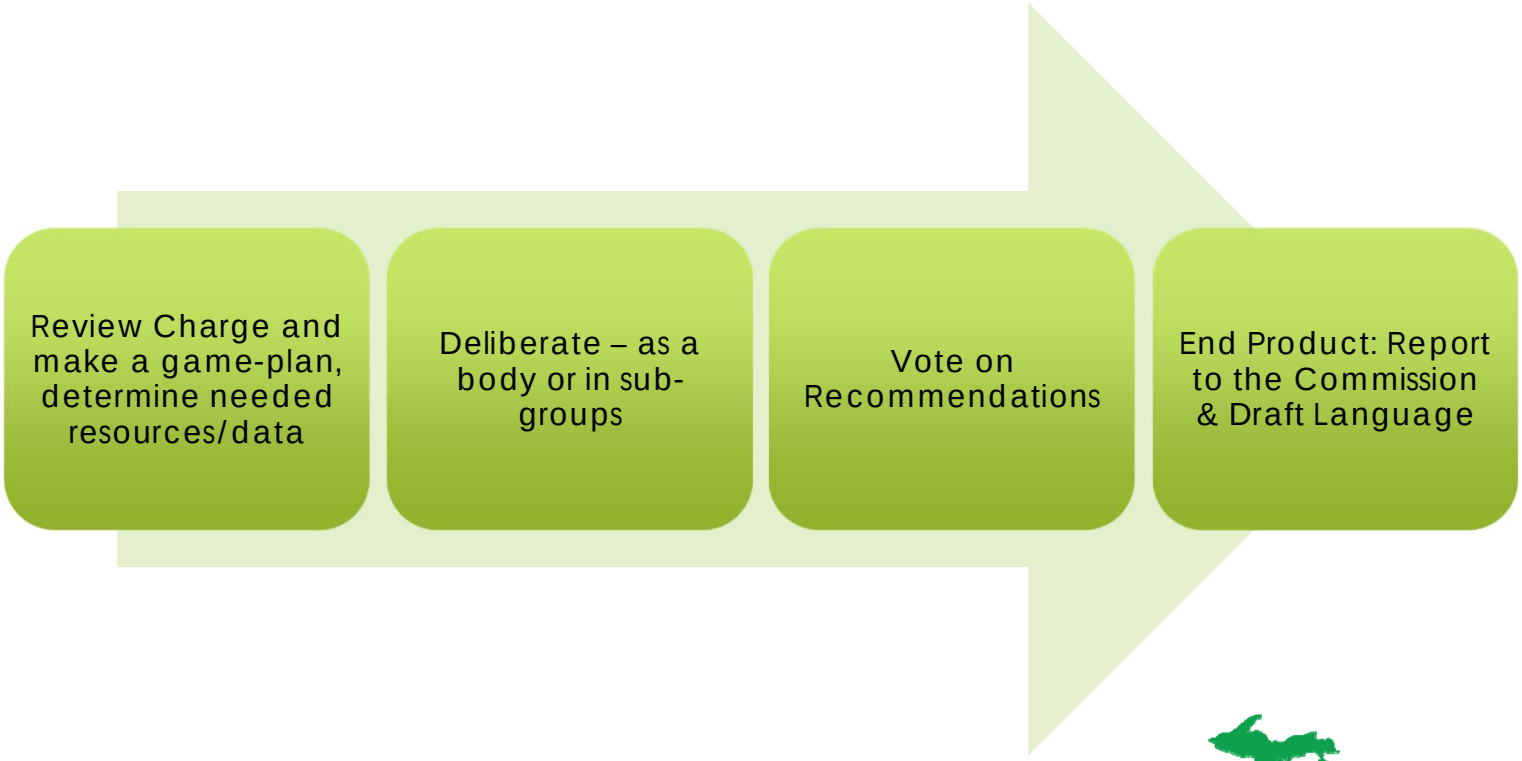
MDHHS
Michigan Department of Health & Human Services

Standard Advisory Committee Operations

- Operates using modified Roberts' Rules
- The Chair or a designee (SAC member) appointed by the Chair can run the meeting
- A physical quorum is necessary to conduct business
- Although SAC members may participate by phone; phone participation is not included in the quorum count or a vote
- A quorum is defined as a majority of the members appointed and serving
- Final recommendations are made by the SAC to the CON Commission. The SAC presents a written report and/or final draft language.

MDHHS
Michigan Department of Health & Human Services

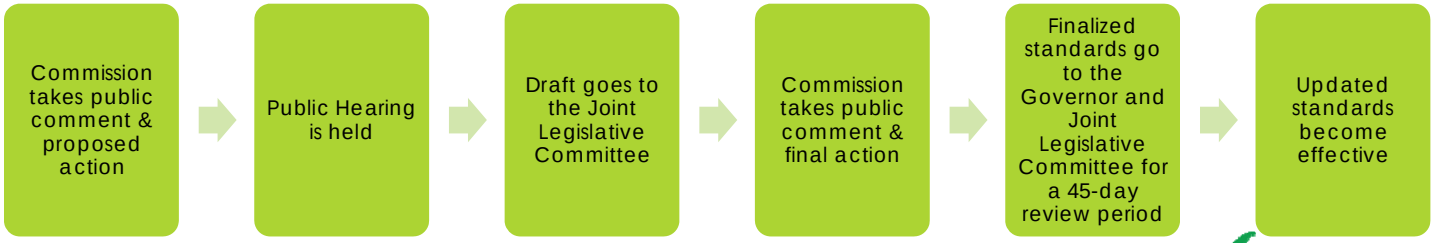
SAC Recommendations Process



MDHHS
Michigan Department of Health & Human Services

After the SAC…

- Recommendations presented to the Commission
- Commission may:
  - Accept the Recommendations
  - Make modifications
  - Reject the Recommendations
- If changes to the Standard are to be made then:



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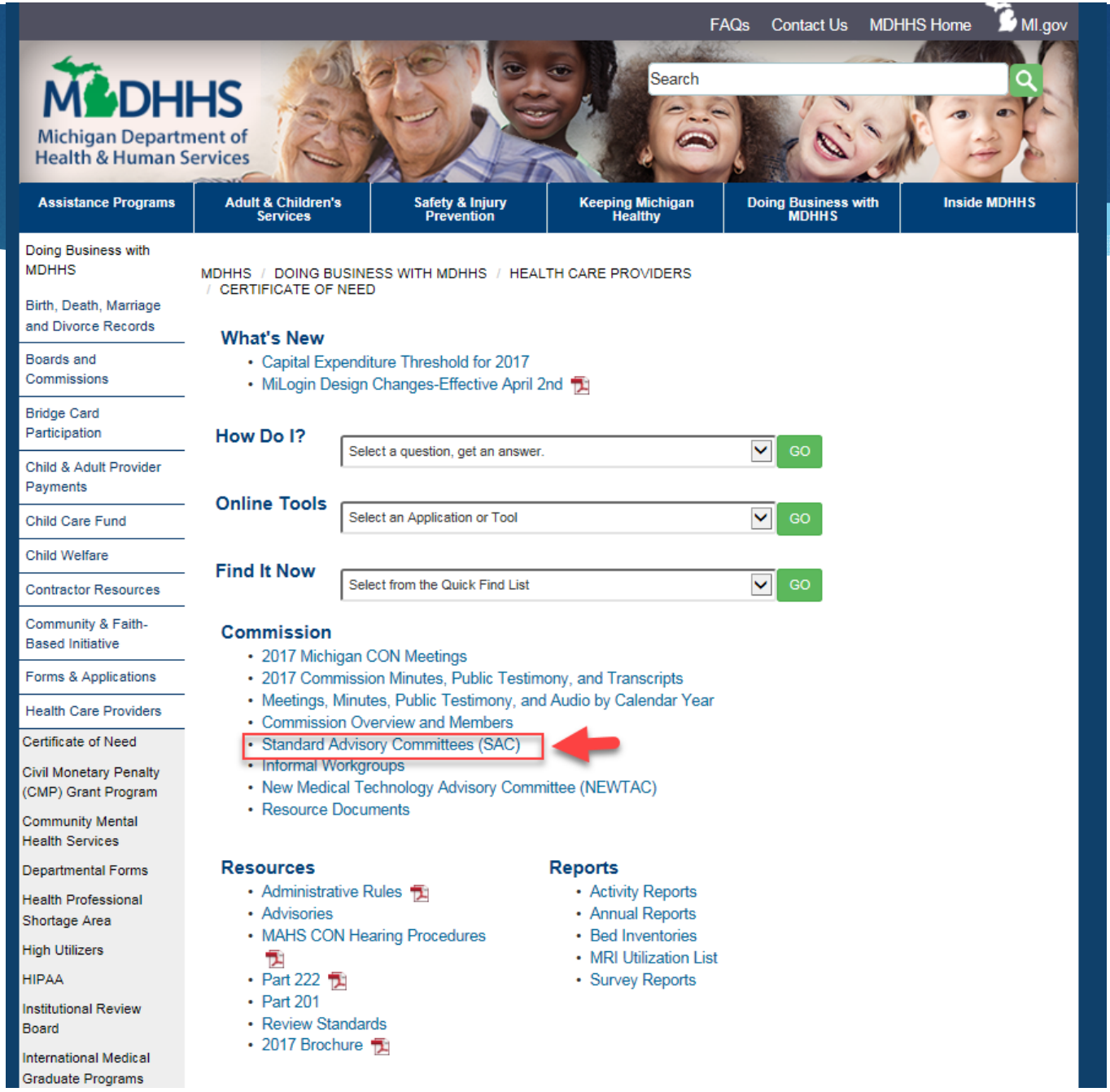
- www.michigan.gov/con



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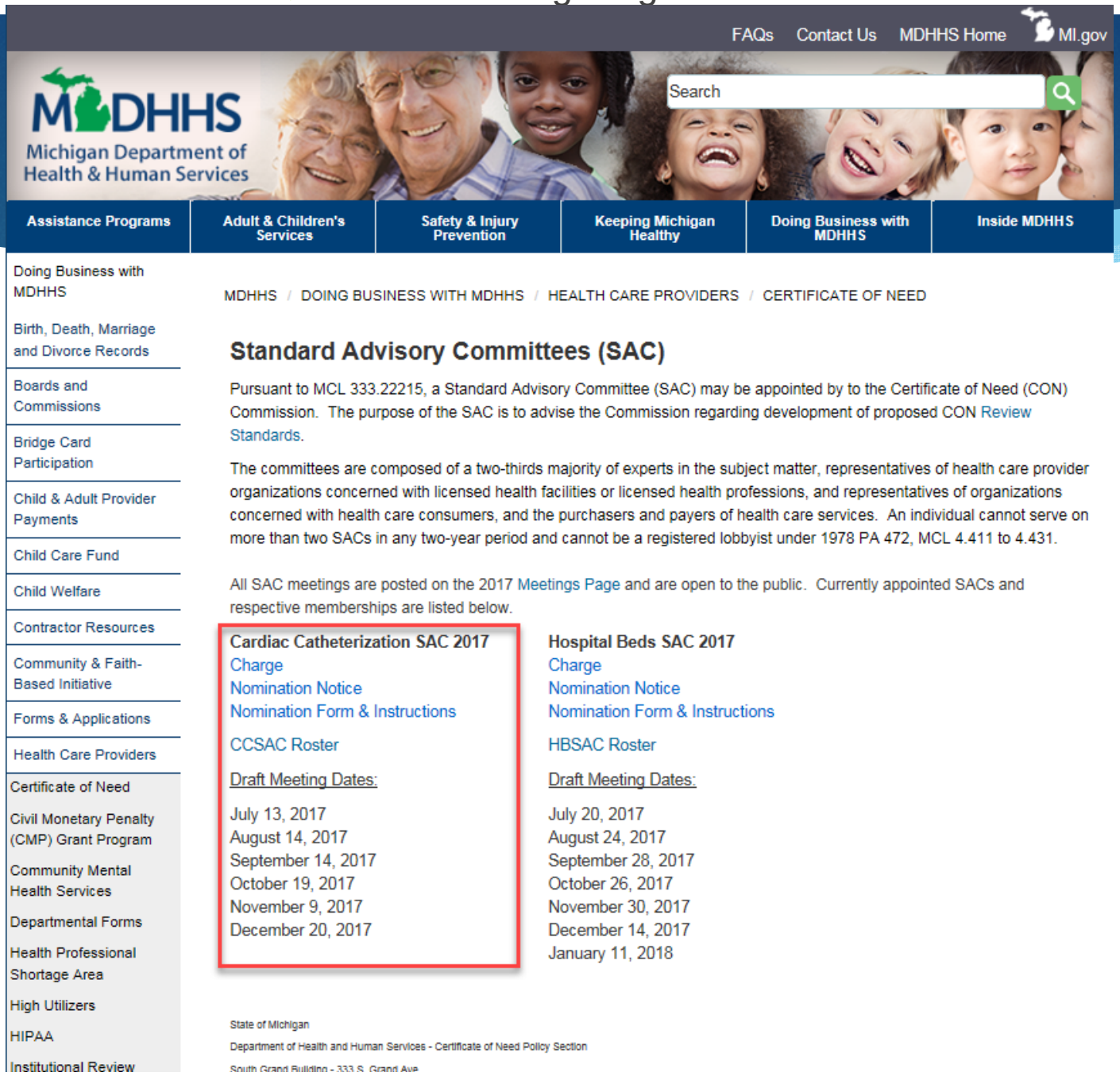

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Bridge Card Participation
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Child Care Fund
Child Welfare
Contractor Resources
Community & Faith-Based Initiative
Forms & Applications
Health Care Providers
Certificate of Need
Civil Monetary Penalty (CMP) Grant Program
Community Mental Health Services
Departmental Forms
Health Professional Shortage Area
High Utilizers
HIPAA
Institutional Review

MDHHS / DOING BUSINESS WITH MDHHS / HEALTH CARE PROVIDERS / CERTIFICATE OF NEED

Standard Advisory Committees (SAC)

Pursuant to MCL 333.22215, a Standard Advisory Committee (SAC) may be appointed by to the Certificate of Need (CON) Commission. The purpose of the SAC is to advise the Commission regarding development of proposed CON Review Standards.

The committees are composed of a two-thirds majority of experts in the subject matter, representatives of health care provider organizations concerned with licensed health facilities or licensed health professions, and representatives of organizations concerned with health care consumers, and the purchasers and payers of health care services. An individual cannot serve on more than two SACs in any two-year period and cannot be a registered lobbyist under 1978 PA 472, MCL 4.411 to 4.431.

All SAC meetings are posted on the 2017 Meetings Page and are open to the public. Currently appointed SACs and respective memberships are listed below.

Cardiac Catheterization SAC 2017
Charge
Nomination Notice
Nomination Form & Instructions

CCSAC Roster

Draft Meeting Dates:

July 13, 2017
August 14, 2017
September 14, 2017
October 19, 2017
November 9, 2017
December 20, 2017

Hospital Beds SAC 2017
Charge
Nomination Notice
Nomination Form & Instructions

HBSAC Roster

Draft Meeting Dates:

July 20, 2017
August 24, 2017
September 28, 2017
October 26, 2017
November 30, 2017
December 14, 2017
January 11, 2018

State of Michigan
Department of Health and Human Services - Certificate of Need Policy Section
South Grand Building - 333 S. Grand Ave

CARDIAC CATHETERIZATION SERVICES

STANDARD ADVISORY COMMITTEE (SAC) CHARGE

As Approved by the CON Commission during the January 26, 2017 meeting

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

Cardiac Catheterization SAC Members	Name of Organizations Nominee is Representing	Current position title	Representing
SAC Chairperson: Shukri David, M.D., MBA, FACC	Ascension | Michigan	Physician Chair, Cardiovascular Center of Excellence, St John Providence Health System, Section Chief, Division of Cardiology, Providence & Providence Park Hospital's, Chief Medical Officer, Cardiovascular Therapeutics, Director- Cardiology Specialty Clinic-Providence Hospital, Clinical Professor of Medicine, Wayne State University-School of Medicine, Detroit, Michigan	Experts
Ernest Balcueva	American Heart Association	Consumer	Consumers
Ibrahim Shah, MD	McLaren Greater Lansing	Chair Department of Cardiology	Experts
Kristopher J. Selke, DO	Mercy Health and Saint Joseph Mercy Health System (members of Trinity Health)	Interventional Cardiologist	Experts
Ryan D. Madder, MD	Spectrum Health	Interventional Cardiologist	Experts
Hitinder S. Gurm, M.D.	University of Michigan Health System	Associate Chief, Division of Cardiovascular Medicine	Experts
Simon R. Dixon, MD	Beaumont Hospital- Royal Oak	Chair, Department of Cardiovascular Medicine, Beaumont Hospital Royal Oak	Experts
Theodore L. Schreiber, MD	Detroit Medical Center	President and Specialist-in-Chief	Experts
Henry E. Kim, MD, MPH, FACC	Henry Ford Health System	Division Head, Cardiovascular Diseases	Experts
Sunita Vadakath, MD, FRCA, MPA	MidMichigan Health	Cardiovascular Service Line Director	Providers
Lynne F. Carter MD,MPH	Blue Cross Blue Shield of Michigan	Associate Medical Director	Payers
Michele L Davis	Electrical Workers' Joint Board of Trustees	Executive Assistant	Purchasers

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR CARDIAC CATHETERIZATION SERVICES

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

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval of the initiation, replacement, expansion, or acquisition of cardiac catheterization services, and the delivery of these services under Part 222 of the Code. Pursuant to Part 222 of the Code, cardiac catheterization services are a covered clinical service. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

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

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

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

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

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

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

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

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

(h) “Elective percutaneous coronary intervention (PCI)” means a PCI procedure performed on a non-emergent basis.

(i) “Elective PCI services without on-site open heart surgery (OHS)” means performing PCI, percutaneous transluminal coronary angioplasty (PTCA), and coronary stent implantation on an organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary PCI service but not having OHS on-site and adhering to patient selection as outlined in the SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site Surgical Backup and published in circulation 2014, 129:2610-2626 and its update or further guideline changes.

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

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

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

(o) “Primary PCI service without on-site OHS” means performing primary PCI on an emergent basis in a hospital having a diagnostic cardiac catheterization service.

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

(q) "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.

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

Section 3. Requirements to initiate cardiac catheterization services

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) The applicant 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 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 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 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 is applying for a primary PCI service without open heart surgery, the applicant shall project a minimum of 36 primary PCI procedures per year.

(b) If the applicant is applying for an elective PCI service without on-site OHS, the applicant shall project a minimum of 200 PCI procedures per year.

(13) If the applicant is applying for an elective PCI service without on-site OHS, the applicant also shall demonstrate the following:

(a) The applicant operated a primary PCI service for at least one year prior to the date of application.

(b) The applicant 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 was not approved as a primary PCI service prior to September 14, 2015, then, in addition, the applicant 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 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 shall apply to initiate primary or elective PCI services without on-site OHS using this section. The applicant 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 proposing to replace a cardiac catheterization laboratory or service shall demonstrate the following as applicable to the proposed project:

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

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

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

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

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

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

(a) The proposed project is part of an application to replace the entire hospital.

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

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

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

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

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

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

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

(c) The existing cardiac catheterization service has been in operation for at least 36 months as of the date the application has been submitted to the Department.

Section 6. Requirements to expand a cardiac catheterization service

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

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

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

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

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

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

Section 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 proposing to acquire a cardiac catheterization service or renew a lease for equipment shall demonstrate the following as applicable to the proposed project:

(1) An applicant proposing to acquire a cardiac catheterization service shall demonstrate the following:

(a) The proposed project is part of an application to acquire the entire hospital.

(b) An application for the first acquisition of an existing cardiac catheterization service after February 27, 2012 shall not be required to be in compliance with the applicable volume requirements in 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 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 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 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 proposing to add one or more hybrid OR/CCLs at an existing cardiac catheterization service shall demonstrate each of the following:

(1) The applicant operates an 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 section 5(2) of these standards.

(3) If the hybrid OR/CCL(s) represents an increase in the number of cardiac catheterization laboratories at the facility, the applicant is in compliance with Section 6 of these standards.

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

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

(6) Each case performed in a hybrid OR/CCL shall be included either in the surgical volume or the therapeutic cardiac catheterization volume of the facility. No case shall be counted more than once.

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

Section 9. **Requirement for Medicaid participation**

Sec. 9. An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. An applicant that is initiating a new service or is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

Section 10. Project delivery requirements and terms of approval for all applicants

Sec. 10. An applicant shall agree that, if approved, the cardiac catheterization service and all existing and approved laboratories shall be delivered in compliance with the following terms of approval:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory located within a hospital, and have within, or immediately available to the room, dedicated emergency equipment to manage cardiovascular emergencies.

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

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

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

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

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

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

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

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

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

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

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

(iii) have each performed a minimum of 50 adult therapeutic cardiac catheterization procedures in the preceding 12 months.

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

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

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

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

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

(j) A cardiac catheterization service shall be directed by an appropriately trained physician. The Department shall consider appropriate training of the director if the physician is board certified in cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable. The director of an adult cardiac catheterization service shall have performed at least 100 catheterizations per year during each of the five preceding years. The Department may accept other evidence that the director is appropriately trained.

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

(l) 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 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.

(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) 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.

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

Section 12. Documentation of projections

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

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

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

(3) An applicant 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 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 and effective on June 2, 2014.

1

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.

MDHHS Recommendations for CON Standards Scheduled for 2017 Review

Cardiac Catheterization (CC) Services Standards			
Department Recommendations: CC should continue to be regulated by CON. The Commission should form a standard advisory committee (SAC) to make a recommendation regarding the issues outlined below.			
Identified Issues	**Issue Recommended for Substantive Review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Modify Sec. 10(5)(f) to apply only to facilities that do not have on-site open heart surgery (OHS). Currently states "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."	No.	Form a SAC if necessary to advise on technical changes.	This change was made during the most recent Standard Advisory Committee (SAC). The Department does not support making a policy change to this requirement. Many open heart surgery programs have already successfully demonstrated compliance with this requirement. This is an important quality of care requirement.
Should pacemakers and implantable cardioverter defibrillator (ICD) implants be allowed to be performed in ambulatory surgical centers (ASCs) or only in licensed hospitals?	Yes.	Form a SAC to review the issue.	The current definition of diagnostic CC services specifies that the services must be performed in a hospital. This issue may also require a change in the Surgical Services standards.
Relax the definition of Primary Percutaneous Coronary Intervention (PCI).	Yes.	Form a SAC to review the issue.	See comments from Beaumont Health.
Review Section 10 (5)(c) – Door-to-Balloon Time requirement to exclude patients with cardiogenic shock who often require intensive resuscitation and medical stabilization before revascularization.	Yes.	Form a SAC to review the issue.	

Review Section 11 – Cardiac Cath Equivalents: including Watchman, Chronic Total Occlusion Percutaneous Coronary Intervention, IMPELLA, paravalvular leak closure and alcohol septal ablation. Possibly incorporating into the cardiac cath equivalent methodology with a weighting of 4.0 (same as Complex percutaneous valvular sessions)."	Yes.	Form a SAC to review the issue.	
Review volume, quality, cost and patient experience for improvements as well as assign relative weights for each.	No.		Refer to comments from Theodore Schreiber, MD and Kyle Sheiko. These standards already address this issue and was part of the most recent updates to the standards.
Make publicly available reports on both the volume of elective and emergency angioplasty being performed at each facility as well as some objective, third-party assessment of quality of services being provided.	No.		Department has reviewed this issue during the most recent SAC and has found this proposal outside of the scope of the CON program.
Clarification on Section 4(13)(a) (Are 36 primary PCI cases needed for approval?) and (b) (What is "acceptable performance?")	Yes.	Form a SAC to review the issue.	This issue was identified by the MDHHS CON Evaluation section.
Review the following definitions and the procedures that are allowed: diagnostic cardiac catheterization service, primary PCI service without on-site OHS, elective PCI services without on-site OHS, therapeutic cardiac catheterization service, and electrophysiology study.	Yes.	Form a SAC to review the issue.	This issue was identified by the MDHHS CON Evaluation section.
Add requirements for replacing an existing CC service from one existing licensed hospital to another existing licensed hospital with certain requirements (e.g., common	Yes.	Form a SAC to review the issue.	This issue was identified by the MDHHS CON Evaluation section. Under current standards, a hospital can only replace a CC service to a

ownership, 5-10 mile relocation zone, ability to meet the initiation requirements, etc.).			new site as part of a consolidated hospital replacement project.
Other technical edits by the Department if needed.			

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "…review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the CC Services Standards are scheduled for review in calendar year 2017.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 7 - 21, 2016. Testimony was received from eight (8) organizations and is summarized as follows:

1. *Barbara Bressack, Henry Ford Health System (HFHS)*
    - HFHS recommends clarification of Sec. 10(5)(f) which states "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." They feel that this is an added burden on existing programs with on-site open heart surgery (OHS) that is unnecessary and unintended by the SAC. They request that the language be clarified to have this requirement only apply to CC facilities that do not have on-site OHS.

2. *David Walker on behalf of Penny Wilton, Spectrum Health*
    - The Centers for Medicare & Medicaid Services recently approved pacemakers and implantable cardioverter defibrillator (ICD) implants can be performed in ambulatory surgical centers (ASCs). Spectrum Health recommends that the standards be updated to make it clear that they must be performed in a licensed hospital. Further, they believe that the word "hospital" was inadvertently removed from the standards since historically they limited CC services to hospitals only.

3. *Steven Szelag on behalf of T. Anthony Denton, University of Michigan Health Systems (UMHS)*
    - UMHS would like the CON Commission to provide clarification and consider a technical revision(s), if recommended, regarding Section 10(5)(f) which states "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." They do not believe that this should be applicable to replacement of an Electro-physiology (EP) laboratory for programs with an on-site OHS service.

4. *Sean Gehle, Ascension Michigan*
    - Supports continued regulation of CC Services and recommends no changes at this time.

5. *Monica Harrison on behalf of Patrick O'Donovan, Beaumont Health*
    - Beaumont states that the definition of "Primary Percutaneous Coronary Intervention (PCI)" is too restrictive in that some patients without ST-segment elevation are appropriate candidates for emergency intervention. They propose the following definition: "Primary percutaneous coronary intervention (PCI) means PCI performed on an emergent basis for acute ST-segment elevation myocardial infarction (STEMI), posterior wall MI, or cardiogenic shock secondary to left ventricular or right ventricular failure from acute myocardial ischemia."
    - Section 10 (5)(c) – Door-to-Balloon Time requirement should exclude patients with cardiogenic shock who often require intensive resuscitation and medical stabilization before revascularization.
    - Section 10 (5)(f) – Beaumont Health recommends that open heart facilities not be required to meet this requirement as these facilities are already required to meet stringent quality standards and protocols.
    - Section 11 – Cardiac Cath Equivalents: Beaumont Health states that "There are additional interventional procedures that are performed in a cath lab but are not identified or weighted in the current cardiac cath equivalent methodology. These include Watchman, Chronic Total Occlusion Percutaneous Coronary Intervention, IMPELLA, paravalvular leak closure and alcohol septal ablation. Beaumont Health recommends these additional procedures be incorporated into the cardiac cath equivalent methodology with a weighting of 4.0 (same as Complex percutaneous valvular sessions)."

6. *Maysoon Abu-Omarah on behalf of Theodore Schreiber, MD, FACC, The DMC Heart Hospital and Cardiovascular Institute, and Kyle Sheiko, Cardiology Service Line*
    - Volume: It is stated that cardiac catheterization services "should not be solely regulated by specific procedural volume alone, but should include the total practitioners lab volume and all surgical volume performed by each practitioner whether it is a closed heart operation or open heart operation on the great vessels within the chest. Further, by utilizing SCAI/ACC/AHA Expert Consensus Document: for Cardiac catheterization Laboratories, CON can incorporate the most current recommendations for institutional and operator performance.
    - Quality: They believe that "the first step is to collaborate with the business intelligence designated for both OHS programs and CCS's (i.e. ACC/AHA, ACS, NCDR and STS Registry) for evidenced based practice as well as for quality data submission and tracking. Additionally we believe accreditation should be a requirement for all CCL's. Detroit Medical Centers Cardiovascular Departments recommends annual reporting of the following cardiac cath quality indicators."
        - ✓ Procedural Appropriateness

- ✓ Door to Balloon (DTB)
- ✓ Risk Adjusted 30 day Readmissions
- ✓ Risk Adjusted 30 day Mortality
- ✓ Discharge medication compliance

- Cost: Suggest the development of collaborative approaches that combine strong clinical outcomes with effective cost containment, i.e., tracking wage severity adjusted cost and severity adjusted length of stay (LOS) is paramount.
- Patient Experience: Improve patient experience, improve patient outcomes while reducing cost is a goal of "Triple Aim" developed by the Institute of Healthcare Improvement (IHI).
- They recommend not only taking into consideration the four components of volume, quality, cost and patient experience but additionally assign relative weights for each.

7. *Dennis McCafferty, Economic Alliance for Michigan (EAM)*
    - EAM would like to see publicly available reports on both the volume of elective and emergency angioplasty being performed at each facility as well as some objective, third-party assessment of quality of services being provided.

8. *Arlene Elliott on behalf of Trinity Health Michigan*
    - Suggest reviewing the applicability of the project delivery requirements as currently written under Section 10(5)(f). "The SCAI/ACC Expert Consensus Document referenced in this project delivery requirement was developed specifically for programs without on-site open heart surgery. To our knowledge and that of our interventional cardiologists, SCAI/ACC has never published a specific guideline that defines facility requirements or cardiologist-heart surgeon relationship requirements for facilities that provide open heart surgery ("OHS"). We do not believe the CON Commission intended to apply expert guidelines designed for one type of facility (without OHS) to a wholly different type of facility (with OHS). Therefore, we would suggest a workgroup be convened to address alternative metrics for quality assurance that are appropriate for cardiac catheterization services with on-site open heart surgery."

Background:

The CC standards were reviewed with a standard advisory committee (SAC) in 2014. The current effective date of the CC standards is September 14, 2015.

CC Survey Data for 2015:

Annual survey data for 2015 is the latest available and can be found here:

Cardiac Catheterization Services –
Adult http://www.michigan.gov/documents/mdhhs/Report_060_-_Cardiac_Catheterization_Services-Adult_538296_7.pdf

Cardiac Catheterization Services –
Pediatric http://www.michigan.gov/documents/mdhhs/Report_062_-_Cardiac_Catheterization_Services-Pediatric_538297_7.pdf

2015 Michigan Certificate of Need Annual Survey
Adult Cardiac Catheterization Services
Report 060

Facility Number	Facility Name	Number of Labs	Hybrid OR/ CC Labs	Highest Level Cardiac Cath*	Number of Sessions			
					Diagnostic CC & Peripherals	Therapeutic CC & Peripherals	Complex Percutaneous Valvular	CC/EP Pediatric Age Patients**
50.0060	MCLAREN MACOMB	3	0	TCC	737	830	0	0
50.0070	ST. JOHN MACOMB OAKLAND HOSP- WARREN	3	0	TCC	1,102	1,444	0	0
50.0110	HENRY FORD MACOMB HOSPITAL	3	0	TCC	1,403	989	0	1
58.0030	PROMEDICA MONROE REGIONAL HOSPITAL	1	0	DCC	392	45	0	0
63.0014	HURON VALLEY-SINAI HOSPITAL	1	0	PPCI	345	270	0	0
63.0030	BEAUMONT HOSPITAL - ROYAL OAK	11	1	TCC	2,976	4,215	125	0
63.0050	BEAUMONT HOSPITAL - FARMINGTON HILLS	1	0	PPCI	701	568	0	0
63.0070	CRITTENTON HOSPITAL MEDICAL CENTER	3	0	TCC	1,244	509	0	0
63.0080	ST. JOHN MACOMB OAKLAND HOSP-MADISON HTS	1	0	DCC	26	15	0	0
63.0120	MCLAREN OAKLAND	1	0	DCC	158	0	0	0
63.0130	PROVIDENCE HOSPITAL AND MEDICAL CENTER	6	0	TCC	1,785	1,804	7	0
63.0140	ST. JOSEPH MERCY OAKLAND HOSPITAL	4	0	TCC	990	1,555	35	0
63.0160	BEAUMONT HOSPITAL - TROY	3	0	TCC	2,544	977	0	0
63.0176	HENRY FORD WEST BLOOMFIELD HOSPITAL	2	0	PPCI	296	45	0	0
63.0177	PROVIDENCE MEDICAL CENTER-PROVIDENCE PAR	2	0	PPCI	455	647	0	0
74.0010	LAKE HURON MEDICAL CENTER	1	0	DCC	195	42	0	0
74.0020	MCLAREN PORT HURON	3	0	TCC	1,730	600	0	0
74.0030	ST. JOHN RIVER DISTRICT HOSPITAL	1	0	DCC	9	2	0	0
81.0030	ST. JOSEPH MERCY ANN ARBOR HOSPITAL	6	1	TCC	2,227	2,246	0	0
81.0060	UNIVERSITY OF MICHIGAN HOSPITALS	9	0	TCC	3,251	2,724	99	0
82.0010	BEAUMONT HOSPITAL - WAYNE	2	0	PPCI	529	102	0	0
82.0030	BEAUMONT HOSPITAL - GROSSE POINTE	1	0	PPCI	348	91	0	0
82.0070	GARDEN CITY HOSPITAL	1	1	PPCI	409	87	0	0
82.0120	BEAUMONT HOSPITAL - DEARBORN	7	1	TCC	1,951	2,561	47	0
82.0170	BEAUMONT HOSPITAL - TRENTON	2	0	PPCI	746	165	0	0
82.0190	ST. MARY MERCY LIVONIA HOSPITAL	2	0	PPCI	633	692	0	0
82.0230	HENRY FORD WYANDOTTE HOSPITAL	2	0	PPCI	494	578	0	0

* DCC - Diagnostic Cardiac Cath Service, PPCI - Diagnostic with primary PCI, EPCI - Diagnostic with elective PCI, TCC - Therapeutic Cardiac Cath Service
**Pediatric age patients (<18 years for CC and <14 years for EP) at adult programs.

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2015 Michigan Certificate of Need Annual Survey
Adult Cardiac Catheterization Services
Report 060

Facility Number	Facility Name		Number of Labs	Hybrid OR/ CC Labs	Highest Level Cardiac Cath*	Number of Sessions			
						Diagnostic CC & Peripherals	Therapeutic CC & Peripherals	Complex Percutaneous Valvular	CC/EP Pediatric Age Patients**
83.0080	CHILDREN'S HOSPITAL OF MICHIGAN		0	0	TCC	77	105	9	0
83.0190	HENRY FORD HOSPITAL		7	1	TCC	2,538	2,329	264	0
83.0220	HARPER UNIVERSITY HOSPITAL		6	0	TCC	5,990	2,656	108	0
83.0420	ST. JOHN HOSPITAL & MEDICAL CENTER		8	1	TCC	1,432	2,493	0	0
83.0450	SINAI-GRACE HOSPITAL		3	0	TCC	2,384	1,126	0	0
HSA 1: SOUTHEAST MICHIGAN		32 Facilities	106	6		40,097	32,512	694	1
33.0020	MCLAREN - GREATER LANSING		5	0	TCC	1,342	540	0	1
33.0060	EDWARD W SPARROW HOSPITAL		5	0	TCC	2,344	2,762	62	0
38.0010	ALLEGIANCE HEALTH		3	0	TCC	969	1,318	0	0
HSA 2: MID-SOUTHERN		3 Facilities	13	0		4,655	4,620	62	1
11.0050	LAKELAND HOSPITAL, ST. JOSEPH		4	0	TCC	1,100	1,168	0	0
13.0031	BRONSON BATTLE CREEK HOSPITAL		1	0	DCC	16	0	0	0
39.0010	BORGESS MEDICAL CENTER		6	0	TCC	11,354	4,986	30	0
39.0020	BRONSON METHODIST HOSPITAL		4	0	TCC	791	1,018	0	0
HSA 3: SOUTHWEST		4 Facilities	15	0		13,261	7,172	30	0
41.0040	SPECTRUM HEALTH BUTTERWORTH HOSPITAL		9	0	TCC	4,188	4,048	11	0
41.0060	METROPOLITAN HOSPITAL		2	0	PPCI	1,198	1,193	0	0
41.0080	MERCY HEALTH SAINT MARY'S		1	0	PPCI	494	343	0	0
61.0020	MERCY HEALTH MUSKEGON - MERCY CAMPUS		2	0	TCC	1,269	474	0	0
70.0020	HOLLAND HOSPITAL		1	0	PPCI	340	212	0	0
HSA 4: WEST MICHIGAN		5 Facilities	15	0		7,489	6,270	11	0
25.0040	HURLEY MEDICAL CENTER		1	0	PPCI	649	970	0	0
25.0050	MCLAREN FLINT		6	1	TCC	2,739	3,209	16	0
25.0072	GENESYS REGIONAL MEDICAL CENTER		4	0	TCC	1,115	1,579	12	0
44.0010	MCLAREN-LAPEER REGION		1	0	DCC	81	67	0	0
HSA 5: GENESEE-LAPEER-SHIAWASSEE		4 Facilities	12	1		4,584	5,825	28	0
09.0050	MCLAREN BAY REGION		6	1	TCC	4,620	1,542	0	0

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2015 Michigan Certificate of Need Annual Survey
Adult Cardiac Catheterization Services
Report 060

Facility Number	Facility Name		Number of Labs	Hybrid OR/ CC Labs	Highest Level Cardiac Cath*	Number of Sessions			
						Diagnostic CC & Peripherals	Therapeutic CC & Peripherals	Complex Percutaneous Valvular	CC/EP Pediatric Age Patients**
18.0010	MIDMICHIGAN MEDICAL CENTER CLARE		1	0	DCC	24	12	0	0
29.0010	MIDMICHIGAN MEDICAL CENTER- GRATIOT		1	0	DCC	62	55	0	0
32.0020	HURON MEMORIAL HOSPITAL		1	0	DCC	176	73	0	0
37.0010	MCLAREN - CENTRAL MICHIGAN		1	0	DCC	174	220	0	0
56.0020	MIDMICHIGAN MEDICAL CENTER-MIDLAND		3	0	TCC	1,139	1,307	0	0
65.0010	WEST BRANCH REGIONAL MEDICAL CENTER		1	0	DCC	231	26	0	0
73.0020	COVENANT MEDICAL CENTER - COOPER		5	0	TCC	2,068	1,714	40	0
73.0050	ST. MARY'S OF MICHIGAN		5	0	TCC	1,319	948	0	0
HSA 6: EAST CENTRAL		9 Facilities	24	1		9,813	5,897	40	0
04.0010	ALPENA REGIONAL MEDICAL CENTER		1	0	DCC	105	82	0	0
24.0030	MCLAREN NORTHERN MICHIGAN HOSPITAL		3	0	TCC	1,446	1,760	13	0
28.0010	MUNSON MEDICAL CENTER		5	1	TCC	2,731	2,786	35	0
HSA 7: NORTHERN LOWER		3 Facilities	9	1		4,282	4,628	48	0
52.0050	UP HEALTH SYSTEM-MARQUETTE		4	0	TCC	929	1,509	6	0
HSA 8: UPPER PENINSULA		1 Facility	4	0		929	1,509	6	0
State Total		61 Facilities	198	9	DCC: 13 EPCI: 0 PPCI: 14 TCC: 34	85,110	68,433	919	2

* DCC - Diagnostic Cardiac Cath Service, PPCI - Diagnostic with primary PCI, EPCI - Diagnostic with elective PCI, TCC - Therapeutic Cardiac Cath Service
**Pediatric age patients (<18 years for CC and <14 years for EP) at adult programs.

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2015 Michigan Certificate of Need Annual Survey
Pediatric Cardiac Catheterization Services
Report 062

Facility Number	Facility Name	Type	No. of Labs	Number of Sessions		
				Diagnostic CC and Peripherals	Therapeutic CC and Peripherals	Complex Percutaneous Valvular
81.0060	UNIVERSITY OF MICHIGAN HOSPITALS	H	3	365	448	22
83.0080	CHILDREN'S HOSPITAL OF MICHIGAN	H	2	140	258	4
HSA 1: SOUTHEAST MICHIGAN	2 Facilities		5	505	706	26
41.0040	SPECTRUM HEALTH BUTTERWORTH HOSPITAL	H	1	110	436	9
HSA 4: WEST MICHIGAN	1 Facility		1	110	436	9
State Total	3 Facilities		6	615	1,142	35

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