MICHIGAN DEPARTMENT OF COMMUNITY HEALTH (MDCH)
CARDIAC CATHETERIZATION
STANDARD ADVISORY COMMITTEE (CCSAC) MEETING

Wednesday May 4, 2011

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

APPROVED MINUTES

I. Call to Order

Chairperson Eagle called the meeting to order @ 9:33 a.m.

A. Members Present:

Fouad Ashkar, Garden City Hospital
Bart Berndt, Lakeland Regional Medical Center
Barton Buxton, Ed.D, Lapeer Regional Medical Center
David Dobies, MD, Genesys Regional Medical Center
Kevin Donovan, Muskegon Construction
Basil Dudar, MD, FACC, Beaumont Hospitals
Kim Eagle, MD, Chairperson, University of Michigan Health System
Robert Goodman, MD, MHSA, FACEP, Blue Cross Blue Shield/Blue arrived@ 9:37 a.m.
John Heiser, MD, West MI Cardiothoracic Surgeons, PLC
Barry Lewis, DO, Botsford General Hospital
Michelle Link, Bronson Methodist Hospital
Roland Palmer, Vice-Chairperson, Alliance for Health
Elizabeth J. Pielsticker, MD, Michigan Heart PC
Dagmar Raica, Marquette General Health System arrived @ 9:34 a.m.
Arthur L. Riba, MD, Oakwood Healthcare, Inc.
Theodore Schreiber, MD, Detroit Medical Center
Frank D. Sotille, MD, Crittenton Hospital Medical Center
Douglas W. Weaver, MD, Henry Ford Health System
Lawerence O. Wells, Michigan League for Human Services

B. Michigan Department of Community Health Staff present:

Jessica Austin
Sallie Flanders
William Hart Jr.

Larry Horvath
Natalie Kellogg
Brenda Rogers

II. Declaration of Conflicts of Interest

None.

III. Review of Minutes of April 20, 2011

Vice-Chairperson Palmer briefly summarized the charges, votes, and outcomes from the last CC SAC meeting.

Dr. Weaver advised that there was a motion passed in the previous meeting included the "auto-revoke" language, and expressed concern that it had been deleted. He would like the minutes to reflect the modification so the Commission recognizes the significance of the revocation language.

Motion by Mr. Buxton and seconded by Dr. Lewis to approve the modified minutes from April 20, 2011. Motion Carried.

IV. Review of Agenda

Chairperson Eagle advised he would like to modify the agenda by adding a small survey regarding elective PCI without on-site surgical backup after item VI and before Public comment.

Motion by Chairperson Eagle and seconded by Dr. Dobies to accept the modified agenda. Motion Carried.

V. Presentation on Pacemakers/ICD Implantations within Multi-Purpose Rooms

Dr. Riba gave a brief verbal summary on multi-purpose rooms.

Discussion followed.

Motion by Dr. Sotille and seconded by Dr. Weaver to allow placement of pacemakers/ICDs within an interventional radiology room in a facility that does not have CON approval for CC services. Motion passes in a vote of 10-Yes, 7- NO, and 2- Abstentions.

VI. Review and Discussion of Draft Language

Mr. Horvath gave a brief overview of the draft CC language (see attachment A).

Discussion followed.

Motion by Dr. Riba and seconded by Dr. Dobies to add the following language to the elective PCI piece (before line 200) the applicant is located more than 60 minutes driving time from an existing Open Heart Surgery hospital. Motion failed in a vote of 7- Yes, 9- No, 3- Abstentions.

Motion by Dr. Weaver and seconded by _____ to add the auto revocation language back into the standards. Motion carried in a unanimous vote 19- Yes, 0- No, 0- Abstentions (see attachment B).

Motion by Dr. Goodman and no second to define posed threat in Section 4. Motion Failed.

Break @ 10:58 a.m. - 11:12 a.m.

Mr. Horvath continued his summary of the draft language section by section.

Discussion followed.

Motion by Dr. Weaver and seconded by Mr. Buxton to modify Section 8 line 382 and delete the minimum of 2 appropriately trained staff. Motion failed in a vote of 8- Yes, 8- No, 3- Abstentions.

Motion by Dr. Weaver and seconded by Dr. Lewis to modify Section 8 (2)(g)(iii) the requirement to have performed a minimum of 75 adult therapeutic cardiac catheterization procedures in the preceding 12 months. Motion failed in a vote of 3- Yes, 12- No, and 4 Abstentions.

Motion by Dr. Weaver and seconded by Mr. Buxton to modify Section 8 to strike line 404-406. Motion failed in a vote of 7- Yes, 8- No, and 4- Abstentions.

Motion by Dr. Sotille and seconded by Dr. Schreiber to modify line 394 to ready adult PCI instead of adult therapeutic. Motion failed in a vote of 5- Yes, 8- No, and 6 – Abstentions.

VII. Chairperson Eagle's Survey

Chairperson Eagle passed out a one page survey to be completed by SAC members. It was decided that Ms. Rogers will compile the information from the surveys for future reference when Dr. Eagle presents the SACs findings at the CON Commission meeting in June (see attachment B).

VIII. Public Comment

Ken Nysson, Metro Health

IX. Final Comments

Chairperson Eagle asked the SAC to express their final comments

X. Adjournment

Motion by Dr. Weaver and seconded by Mr. Buxton to adjourn the meeting @ 12:20 p.m. Motion Carried.

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. 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.

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

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

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

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

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

(h) “Elective Percutaneous Coronary Intervention (PCI) Service” means providing percutaneous transluminal coronary angioplasty (PTCA) and coronary stent implantation on an organized, regular basis in a laboratory at a hospital without on-site open heart surgical services. The term does not include transcatheter valve, other structural heart disease procedures, or left sided arrhythmia therapeutic

procedures. A hospital that provides elective PCI services may also perform implantations of cardiac permanent pacemakers, ICD devices, and right sided catheter ablation procedures. Structural heart disease procedures can only be performed within a hospital that has on-site open heart surgical services.

(i) "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 cardiac permanent pacemakers and ICD devices.

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

(k) "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.

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

(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 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.

(o) "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.

(p) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations procedures on an organized, regular basis in a laboratory to treat and resolve anatomical and/or physiological problems in the heart. Procedures include percutaneous coronary intervention (PCI), percutaneous transluminal coronary angioplasty (PTCA), atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker/ICD device implantations, transcatheter valve, other structural heart disease procedures, 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 in a rural or micropolitan statistical area county shall project a minimum of 500 procedure equivalents that includes 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures during the most recent 12-month period preceding the date the application was submitted to the Department for a single laboratory.

(b) An applicant 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 during the most recent 12-month period preceding the date the application was submitted to the Department for a single laboratory.

(c) An applicant proposing to initiate 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 during 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) The applicant 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 adult diagnostic cardiac catheterization service has been in operation more than 24 months.

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

(d) The applicant shall project a minimum of 300 procedure equivalents in the category of adult therapeutic cardiac catheterizations during 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 demonstrates the following:

(i) A board certified pediatric cardiologist with training in pediatric catheterization procedures to direct the pediatric catheterization laboratory.

(ii) Standardized equipment as defined in the most current American Academy of Pediatric (AAP) Guidelines for Pediatric Cardiovascular centers.

(iii) On-site ICU as defined in the most current AAP guidelines above.

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

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

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

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

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

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

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

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

(f) A written agreement with an open heart surgical hospital that includes:

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

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

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

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

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

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

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

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

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

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

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

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

(5) An applicant proposing to initiate an elective PCI service without on-site open heart surgical services 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 elective PCI services.

(b) The applicant has at least two interventional cardiologists to perform PCI procedures at the hospital that meet the following:

(i) Board certified in interventional cardiology.

(ii) Individual outcomes are comparable to national outcomes.

(iii) Performed at least 300 PCI sessions since fellowship.

(iv) Performed at least 100 PCI sessions in each of the most recent two years preceding the date the application was submitted to the Department.

(c) A written agreement with an open heart surgical hospital that includes:

(i) Signatures by senior executives from the applicant hospital and the hospital with open heart surgical services.

(ii) Involvement in the credentialing criteria and recommendations for physicians approved to perform PCI.

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

(iv) 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 to be documented annually.

(v) Regularly held joint cardiology/cardiac surgery conferences (at least quarterly) to include review of all PCI cases and outcomes;

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

(vii) A mechanism to provide for appropriate patient transfers between hospitals and an agreed plan for prompt care; written protocols, signed by the applicant and the open heart surgical hospital, must be in place with provisions for immediate and efficient transfer within one hour of patients requiring surgical evaluation and/or intervention 24 hours per day, 365 days a year. The protocols shall be reviewed/tested on a regular, semi-annual basis.

(viii) Ability to transfer images electronically for the concurrent review of cases with the open heart surgical hospital if needed.

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

(d) The applicant agrees to the following:

(i) A written protocol must be established and maintained for case selection for the performance of PCI that is consistent with current practice guidelines set forth by the American College of Cardiology and the American Heart Association, including a risk stratification tool (STS or SYNTAX) used and recorded to insure appropriate triage to coronary artery bypass graft surgery. Exclusions for elective PCI should include decompensated heart failure without acute ischemia, recent stroke, advanced malignancy, known clotting disorders, EF less than 25%, left main disease unprotected by prior surgery, lesions that jeopardize >50% of myocardium, diffuse disease and excessive tortuosity, degenerated vein grafts, substantial thrombus, aggressive measures to open chronic total occlusions, and inability to protect major side branches.

(ii) Establish and maintain written policy and procedures for training, staffing, and program review.

(iii) The nursing and technical catheterization staff are experienced in handling acutely ill patients and comfortable with interventional equipment; have acquired experience in dedicated interventional laboratories at open heart surgical services or at primary PCI services; and participate in an un-interrupted 24-hour, 365-day call schedule. Competency to be documented annually.

(iv) The catheterization laboratory is equipped with imaging systems, resuscitative equipment, intra-aortic balloon pump (IABP) support, and stocked with appropriate interventional equipment.

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

(vi) Establish and maintain a system to ensure prompt and efficient identification of potential primary PCI patients and rapid transfer to the catheterization laboratory so that door-to-balloon targets are met.

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

(e) The applicant shall project the following, as applicable to the proposed project:

(i) 350 PCI (PTCA and coronary stent) cases during the most recent 12-month period preceding the date the application was submitted to the Department if the hospital is within one hour drive time of an existing PCI or open heart surgical hospital.

(ii) 250 PCI (PTCA and coronary stent) cases during the most recent 12-month period preceding the date the application was submitted to the Department if the hospital is more than one hour drive time of an existing PCI or open heart surgical hospital.

Section 4. Requirements to replace an existing cardiac catheterization laboratory

Sec. 4. Replacing a cardiac catheterization laboratory means a change in the angiography X-ray equipment or a relocation of the service to a new site. The term does not include a change in any of the other equipment or software used in the laboratory. An applicant proposing to replace a cardiac catheterization service or laboratory 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 meetings 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 operations 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 existing cardiac catheterization service is in compliance with the applicable volume requirements:

(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.

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

Section 5. Requirements to expand a cardiac catheterization service

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

(1) The existing cardiac catheterization service is in compliance with the applicable volume requirements:

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

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

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

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

Section 6. Requirements to acquire a cardiac catheterization service

Sec 6. Acquiring a cardiac catheterization services 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 services after <INSERT EFFECTIVE DATE OF THESE STANDARDS> shall not be required to be in compliance with the applicable volume requirements in subdivision (c). The cardiac catheterization service shall be operating at the applicable volumes set forth in the project delivery requirements in the second 12 months of operation of the service by the applicant and annually thereafter:

(c) Except as provided for in subdivision (b), an application for the acquisition of an existing cadiac catheterization service after <INSERT EFFECTIVE DATE OF THESE STANDARDS> shall demonstrate the following, as applicable to the proposed project:

(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.

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

Section 7. Requirement for Medicaid Participation

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

Sec. 8. 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 requirements:

(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 approved 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 number of procedures performed.

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

(e) Each physician credentialed by a hospital to perform pediatric diagnostic cardiac catheterizations shall perform, as the primary operator, a minimum of 50 pediatric diagnostic cardiac catheterization

procedures per year in the second 12 months after being credentialed and annually thereafter. The annual case load for a physician means pediatric diagnostic cardiac catheterization procedures performed by that physician in any combination of hospitals.

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

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

(i) Are trained consistent with the recommendations of the American College of Cardiology.

(ii) Are credentialed by the hospital to perform adult diagnostic cardiac catheterizations.

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

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

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

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

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

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

(i) Is a 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.

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

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

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

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

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

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

(c) The cardiac catheterization 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 cardiac catheterization services shall be operating at 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.
(viii) 350 adult PCI cases for an elective PCI service within one-hour drive time of an existing hospital with an open heart surgical service.
(ix) 250 adult PCI cases for an elective PCI service more than one-hour drive time of an existing hospital with an open heart surgical service.
(b) The hospital shall participate in a data collection network established and administered by the Department or its designee. Data may include, but is not limited to, annual budget and cost information, operating schedules, patient demographics, morbidity and mortality information, and payer sources. The hospital shall provide the required data in a format established by the Department. The Department may verify the data through on-site review of appropriate records.
(c) The hospital shall participate in a quality improvement data registry administered by the Department or its designee. The hospital shall submit summary reports as required by the Department. The hospital is liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. The hospital must become a member of the data registry upon initiation of the service and continue to participate annually thereafter for the life of that service.

(5) Compliance with the following PCI requirements, if applicable:
(a) The hospital shall maintain all quality requirements set forth in subsection 3(4) and 3(5) as applicable to the cardiac catheterization service.
(b) The hospital shall participate in a benchmarked PCI data registry designed by the Department that includes all the following:
(i) Patient and clinical descriptions.
(ii) Measures of outcomes.
(iii) Measure of the ACC appropriate use of the procedure including STS or SYNTAX score in each patient. The Department shall require that the hospital submit data on all PCI cases in a format established by the Department. The hospital shall be liable for costs of data submission. The Department shall require that the hospital submit a summary report on an annual basis that shall be made available to the general public.
(c) The hospital shall participate in an external impartial oversight body to be designated by the Department. The hospital shall be liable for the costs of participating in this oversight process and must continue to participate annually thereafter. The oversight body shall produce an annual report of all PCI program that will contain all the following:
(i) Complication rates.
(ii) Number of procedures performed per operator.
(iii) Success rates.
(iv) Appropriate use rates.
(v) Patient transfer rates.
(vi) The oversight body shall review the findings with each of the participating hospitals as a group and shall provide those findings to the Department to be made available to the general public. All elective PCI services performing less than 250 PCI cases per year in any given year must have all cases reviewed by this oversight body for appropriateness and outcomes.
(d) The hospital shall include in their consent for PCI notification to the patient that the hospital does not provide on-site open heart surgical services and that transfer to a hospital with open heart surgical services may be necessary.
(e) The hospital shall establish an internal review body, including at a minimum the chief medical officer, director of cardiovascular services, director of cardiovascular services for the hospital with open heart surgical services (or equivalent physician representatives), that shall 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 and procedures requiring transfer.
(f) The hospital shall employ appropriate data management personnel to insure timely and accurate reporting to the registry and reviewing bodies stated above.

(g) Each physician credentialed by a hospital to perform PCI cases shall perform, as the primary operator, a minimum of 100 PCI cases per year in the second 12 months after being credentialed and annually thereafter. The annual case load for a physician means PCI cases performed by that physician in any combination of hospitals.

(h)Each physician must also maintain the following in order to be credentialed:

(i) Participation in an institutional quality improvement program.

(ii) Board certified in interventional cardiology.

(iii) Performed at least 300 PCI cases total since fellowship.

(iv) At least 30 hours of continuing medical education directed toward interventional cardiology every 24 months.

(i) The medical director of the hospital shall perform PCI procedures at the contracted hospital with open heart surgical services and shall also perform PCI procedures at the elective PCI service hospital during each year until the hospital reaches minimum volume.

(j) The hospital shall always have in place a written agreement meeting all of the requirements of the written agreement between the hospital and the hospital with the open heart surgical service as long as the elective PCI service does not have on-site open heart surgical services, but may change the contracted open heart surgical hospital.

(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 9. **Methodology for computing cardiac catheterization equivalents**

Sec. 9. The following shall be used in calculating procedure equivalents and evaluating utilization of a cardiac catheterization service and laboratory:

PROCEDURE TYPE	PROCEDURE EQUIVALENT	
	Adult	Pediatric
Diagnostic Cardiac Catheterization/Peripheral Sessions	1.5	2.7
Therapeutic Cardiac Catheterization/Peripheral Sessions	2.7	4.0
Percutaneous Valvular Sessions*	4.0	7.0
*Percutaneous valvular sessions means providing…		

Section 10. Documentation of projections

Sec. 10. An applicant required to project volumes 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. An applicant must also meet the following requirements as applicable to the proposed project:

(1) 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 months 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.

(2) An applicant proposing to initiate an elective PCI service shall demonstrate and certify the following:

(a) Physician commitments of PCI cases performed at an existing cardiac catheterization service in the same health service area.

(i) Commitments of PCI cases shall not reduce an existing cardiac catheterization service below its applicable volume requirement.

(ii) Commitments of PCI cases do not represent duplicate cases with this subsection.

(iii) Commitments identify the following:

(A) The name of each physician that performed PCI cases to be committed to the proposed project.

(B) The number of PCI cases of each physician performed during the most recent 12 months verifiable by the Department.

(C) The locations at which the committed PCI cases were performed.

(D) A written commitment from each physician that he or she will perform at least the volume of PCI cases committed to the proposed cardiac catheterization service for no less than three years subsequent to the initiation of services proposed by the applicant.

(E) The number of PCI cases performed at the existing cardiac catheterization service from which PCI cases will be transferred during the most recent 12 months verifiable by the Department for which annual survey data is available.

(b) Documentation of existing patient transfers from the applicant hospital to an PCI service or open heart surgical hospital for purposes of receiving a PCI procedure. In demonstrating compliance, an applicant shall provide the following for each patient transfer in the most recent 12 months verifiable by the Department:

(i) Unique patient identifier.

(ii) ICD-9, or equivalent, diagnosis code.

(iii) Hospital where the patient was transferred.

(iv) Physician patient transferred to.

(v) Date of patient transfer.

(c) Existing PCI cases performed at the applicant hospital in the most recent 12 months verifiable by the Department.

Section 11. Comparative Reviews; Effect on prior CON Review Standards

Sec. 11. Proposed projects reviewed under these standards shall not be subject to comparative review. These standards supersede and replace the CON Review Standards for Cardiac Catheterization Services approved by the CON Commission on December 11, 2007 and effective on February 25, 2008.

Appendix A

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

APPENDIX B

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

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

Proposed Amendment to Section 3(1)

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) THE APPLICANT IS APPLYING TO PROVIDE ADULT THERAPEUTIC CARDIAC CATHETERIZATION OR ELECTIVE PCI SERVICES AT THE HOSPITAL. THE APPLICANT MUST BE APPROVED FOR ADULT THERAPEUTIC CARDIAC CATHETERIZATION OR ELECTIVE PCI SERVICES IN ORDER TO BE APPROVED FOR ADULT DIAGNOSTIC CARDIAC CATHETERIZATION SERVICES.

(b) An applicant in a rural or micropolitan statistical area county shall project a minimum of 500 procedure equivalents that includes 300 procedure equivalents in the category of diagnostic cardiac catheterization procedures during the most recent 12-month period preceding the date the application was submitted to the Department for a single laboratory.

(c) An applicant 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 during the most recent 12-month period preceding the date the application was submitted to the Department for a single laboratory.

(d) An applicant proposing to initiate 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 during the most recent 12-month period preceding the date the application was submitted to the Department.