

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

Thursday June 9, 2011

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

APPROVED MINUTES

I. Call to Order & Introductions

Introductions were made by Ms. Dazzo, Mr. Howd, Dr. Cowling, and Mr. Barnett.

Chairperson Falahee called the meeting to order @ 9:36 a.m.

A. Members Present:

James B. Falahee, Jr., JD, Chairperson
Edward B. Goldman, Vice-Chairperson
Bradley Cory
Kathleen Cowling, DO
Charles Gayney
Robert Hughes
Marc Keshishian, MD
Brian Klott
Gay L. Landstrom, RN
Michael A. Sandler, MD

B. Members Absent:

Suresh Mukherji, MD

C. Department of Attorney General Staff:

Ray Howd

D. Michigan Department of Community Health Staff Present:

Olga Dazzo
Melanie Brim

Jessica Austin
Lonnie Barnett
Tulika Bhattacharya
Sallie Flanders
Larry Horvath
Natalie Kellogg
Joette Laseur
Tania Rodriguez
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Keshishian and seconded by Commissioner Hughes to accept the agenda as presented. Motion Carried.

III. Declaration of Conflicts of Interest

Chairperson Falahee provided a brief overview of conflicts of interest. None were noted.

IV. Review of Minutes

Motion by Commissioner Gayney and seconded by Commissioner Landstrom to accept the minutes as presented from the March 24, 2011 meeting. Motion Carried.

V. Computed Tomography (CT) - Public Hearing Comments

Ms. Rogers gave a brief summary of the comments submitted for the April Public Hearing (see attachment A).

A. Public Comment:

Dr. Charles Bill, Sparrow Hospital (see attachment B)

B. Commission Discussion

Discussion followed.

C. Commission Final Action

Motion by Commissioner Sandler and seconded by Commissioner Cory to approve the proposed amendment and move the language forward to a public hearing and the Joint Legislative Committee (JLC). Motion Carried in a vote of 10- Yes, 0- No, 0- Abstained.

VI. Cardiac Catheterization Standard Advisory Committee (CCSAC) Report

Dr. Eagle, CCSAC Chairperson, gave a written and verbal report of the CCSAC's findings (see attachments C & D).

A. Review of Proposed Language

Ms. Rogers provided a written summary and verbal overview of the proposed changes made to the CC language (see attachments E & F).

Break @ 10:57a.m.-11:19 a.m.

B. Public Comment:

Dr. Steve Harrington, Henry Ford Macomb
Craig Banasial, Chrysler Group
Bart Buxton, Lapeer Regional Medical Center
Marsha Manning, General Motors Corp. (see attachment G)
Dr. Mike Jaggi, Hurley Hospital (see attachment H)
Dennis McCafferty, Economic Alliance of Michigan
Dr. Douglas Weaver, Henry Ford Health Systems
Dr. Richard McNamara, West Michigan Heart
Dr. Lawrence Patzett, West Michigan Cardiothoracic Surgeons (see attachment I)
Dr. Georges Ghafarin, Beaumont Hospital Grosse Pointe
Dr. Emmanuel Papasavakis, Garden City Hospital
Susan Heck, Corazon for Hurley Hospital (see attachment J)
Deidre Wilson, Blue Cross Blue Shield
Eric McBride, Oakwood Healthcare Inc.
Robert Meeker, Spectrum Health

C. Commission Discussion

Discussion followed.

D. Commission Proposed Action

Mr. Howd agreed to research the auto revoke language within the CC standards to legally define the impact it will have on the Department's capabilities of enforcement.

Motion by Commissioner Sandler and seconded by Commissioner Landstrom to send the proposed language, including the two amendments that were discussed (ref. line 414 & 890) to public

hearing and the JLC. Motion Failed in a vote of 5- Yes, 5- No, and 0-Abstained.

Motion by Vice-Chairperson Goldman and seconded by Commissioner Sandler requesting that the Department draft language striking the de-coupling language in Section 3(5), and amend the standards to preclude the elective PCI without on-site surgical back-up. Motion Carried in a vote of 7- Yes, 3- No, 0- Abstained.

Motion by Commissioner Sandler and seconded by Commissioner Landstrom to revisit the elective PCI without on-site surgical back-up (de-coupling language) when the ACC guidelines are published. Motion Failed in a vote of 5- Yes, 4-No, 1- Abstained.

Break @ 1:48 p.m. - 2:02 p.m.

VII. Megavoltage Radiation Therapy (MRT)

A. Review of Proposed Language

Mr. Horvath gave a brief overview of the changes to the proposed language (see attachments K & L).

B. Public Comment

Bob Meeker, Spectrum Health
Andrew Teresi, DMC

C. Commission Discussion

Discussion followed.

D. Commission Proposed Action

Motion by Commissioner Sandler and seconded by Commissioner Gayney to move the proposed language forward to public hearing and the JLC. Motion Carried in a vote of 7- Yes, 3- No, 0- Abstained.

VIII. Magnetic Resonance Imaging (MRI) Services- Intra-Operative MRI (iMRI)

A. Review of Proposed Language

Ms. Rogers gave a brief overview of the changes to the iMRI proposed language within the standards (see attachment M).

B. Public Comment

None

C. Commission Discussion

None.

D. Commission Proposed Action

Motion by Vice-Chairperson Goldman and seconded by Commissioner Cory to approve the proposed language and move it forward to public hearing and the JLC. Motion Carried in a vote of 8-Yes, 0- No, and 0- Abstained.

IX. Positron Emission Tomography (PET)

A. Review of Proposed Language

Ms. Rogers gave a brief overview of the changes to the proposed language (see attachments N & O).

B. Public Comment

None

C. Commission Discussion

None

D. Commission Proposed Action

Motion by Commissioner Keshishian and seconded by Commissioner Sandler to approve the proposed language and move it forward to public hearing and the JLC. Motion Carried in a vote of 8-Yes, 0- No, and 0- Abstained.

X. Standing New Medical Technology Advisory Committee (NEWTAC)

Commissioner Keshishian advised no NEWTAC meetings have been held.

XI. Legislative Report

Mr. Barnett gave a verbal legislative report.

XII. Administrative Update

A. Health policy Section Update

Mr. Barnett gave a brief administrative update.

Ms. Rogers gave a brief Health Policy update.

B. CON Evaluation Section Update

1. Compliance Report (Written Report)

Mr. Horvath gave a summary of the Compliance Report (see attachment P).

2. Quarterly Performance Measures (Written Report)

Mr. Horvath gave a summary of the Quarterly Report (see attachment Q).

3. Web Site Update

4. 2011 CON Seminar

5. 2010 Annual Survey

6. Mapping Update

On behalf of the Commission, Chairperson Falahee thanked Mr. Horvath for his work.

XIII. Legal Activity Report

Mr. Howd provided a summary of the legal activity report (see attachment R).

XIV. Future Meeting Dates

A. September 22, 2011

B. December 15, 2011

XV. Public Comment

Dennis McCafferty, EAM

XVI. Review of Commission Work Plan

A. Commission Discussion

Ms. Rogers gave a brief summary of the drafted work plan for the Commission (see attachment S).

Discussion followed, and it was decided to add Open Heart Surgery to the September 22, 2011 meeting agenda.

B. Commission Action

Motion by Vice-Chairperson Goldman and seconded by Commissioner Sandler to accept the draft work plan as amended.
Motion Carried.

XVII. Adjournment

Motion by Commissioner Sandler and seconded by Commissioner Klott to adjourn the meeting @ 2:39 p.m. Motion Carried.

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

Date: May 16, 2011
TO: Brenda Rogers
FROM: Natalie Kellogg
RE: Summary of Public Hearing Comments on Computed Tomography (CT) Services Standards and MDCH Policy Staff Analysis

Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the CT Standards at its March 24, 2011 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed CT Standards on April 26, 2011. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was received from one organization and is summarized as follows:

Melissa Cupp, Wiener Associates

Sparrow Hospital supports the continued regulation of CT services but has some concerns about the portable CT pilot provisions proposed within the standards. Sparrow expressed concern over the project delivery requirements that limit the use of a portable CT to the ICU. Sparrow insists that they could clearly purchase 2 separate, yet identical portable CT units and meet all CON requirements, but clearly it makes most economic sense for the hospital to purchase 1 unit that can be utilized in both the ICU and the OR.

Staff Analysis and Recommendations

The Department has no position to adding language that would allow the use of a portable CT in an OR. The Department supports the CON Commission's March 24, 2011 proposed action as written or modified if the Commission so chooses.

Sparrow Amendment to CT Standards

Amend Project Delivery Requirements as follows:

(5) An applicant approved under Section 13 shall be in compliance with the following:

(A) PORTABLE CT SCANNER CAN ONLY BE USED BY A QUALIFYING PILOT PROGRAM FOR THE FOLLOWING PURPOSES:

(I) BRAIN SCANNING OF PATIENTS BEING TREATED IN AN ADULT OR PEDIATRIC INTENSIVE CARE UNITS (ICU).

(II) NON-DIAGNOSTIC, INTRA-OPERATIVE GUIDANCE IN AN OPERATING ROOM.

Chair Comments to the CON Commission

Prepared by Kim A. Eagle, MD

1. Population of Michigan is shrinking
2. Through prevention efforts and better medical treatments, the need for coronary revascularization is going down
3. Access is not a major issue with the vast majority of Michigan's residents
4. The SAC was nearly unanimous on its recommendations for:
 - Cardiac Cath Services should continue to be regulated
 - Methodology for determining procedure equivalents should be simplified
 - Counting procedures to meet minimum volume requirements
 - Agreement to adjust minimum annual volume requirements for PCI
 - How to add new therapeutic procedures to the mix of volume requirements
 - The SAC worked with the MDCH staff to clarify issues regarding replace vs. upgrade activities and supports the proposed language
5. The SAC was essentially split equally regarding the possibility of changing the standards to allow hospitals to perform elective PCI in the absence of on-site cardiac surgery backup.
The "Pro" side of this debate included representatives from seven health systems:

- | | |
|----------------------------|-------------------------|
| • Botsford Hospital | • Hurley Medical Center |
| • Detroit Medical Center | • Metro Health |
| • Garden City Hospital | • Trinity Health |
| • Henry Ford Health System | |

This coalition hired a consulting agency, brought in an "expert" physician to argue their side of the debate, and approached SAC committee members off line to argue their cause, and assess where the committee stood on this issue. In a surprise move, at the SAC's third meeting, before the SAC had an opportunity to fully assess the data, a member of the SAC (employed by a Health System in the coalition) called for an early vote to approve in principle elective PCI without surgical back-up . It was clear that this vote was encouraged by the coalition because it felt confident that it had the needed votes to pass. A heated debate was followed by a vote...10 to 9, in favor. Every member of the SAC employed by 1 of the health system coalition members voted in favor. The difficulty with this approach was that it seemed to be driven by a pre-conceived decision rather than being the outcome of discussion following analysis of the data.

Meanwhile, the Economic Alliance was communicating with SAC Committee members and was against the proposed plan. Similarly, the state's Society of Thoracic Surgery weighed in against the proposal (Attachment A). When the committee revoted on the question of allowing elective PCI without surgical backup, the vote was 9 in favor, 8 against. The chair was not able to attend that meeting but would have voted against if he had been there. Essentially, the committee is evenly divided on this issue. The arguments for and against this idea are listed below:

Elective PCI without Surgical Backup should be allowed

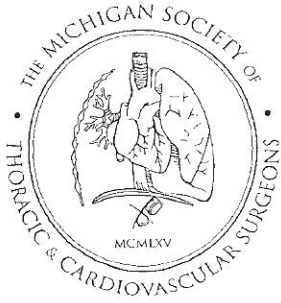
- Most US states now allow this
- It could improve geographic access to elective PCI
- With proper credentialing, monitoring, audit, and oversight, it should be safe
- It will help some health systems to regionalize care nearer to patients they serve
- Some borderline volume cardiac surgery programs might close – a theoretic cost improvement

Elective PCI without Surgical backup should NOT be allowed

- Michigan already has many low volume operators – this provision will encourage more
- Expansion of therapeutic catheterization services will increase inappropriate procedures, increase costs and reduce overall quality of care
- With overall PCI rates going down, there is no need for expansion
- The state lacks the infrastructure and will to close under performing programs

The final language in the SAC document includes the provision for this possibility (elective PCI without onsite cardiac surgery) but with suggestions for monitoring and recommendations about closing programs that fail to reach safety, quality, volume, or appropriateness benchmarks. The recommended quality, safety, volume, and appropriateness oversight is consistent with the activities of New York State, which has a very tightly controlled program.

In order to provide the CON Commission with even more granular thoughts and concerns about therapeutic PCI without onsite cardiac surgery, the chair surveyed the feelings of each member, asking for them to vote on what this might mean to access, safety, quality, cost, and appropriateness of coronary care for the citizens of Michigan. Also, he asked for committee members to share individual comments about this. The responses were tabulated by staff members of the state. These are summarized in Attachment B.



Eric C. Hanson, MD, FACS
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Harold L. Gallick, MD, FACS
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C. Douglas Lees, MD, FACS
Councilor

Shahrokh Mansoori, MD, FACS
Councilor

Luigi Maresca, MD, FACS
Councilor

James R. Martin, MD, FACS
Councilor

Brad E. Vazales, MD, FACS
Councilor

ANNUAL APPOINTMENTS

Joseph S. Bassett, MD, FACS
Senior Councilor

Richard L. Prager, MD, FACS
Peer Review and Quality
Initiative Chair

Allen Silbergleit, MD, FACS
Historian & MSMS Delegate

Frederick R. Armenti, MD, FACS
Representative to MSMS Committee on
Health Care Quality

March 30, 2011

Kim Eagle, M.D.
Albion Walter Hewlett Professor of Internal Medicine
Director, Cardiovascular Center
CVC 2135-B, SPC 5852
1500 E. Medical Center Drive
Ann Arbor, MI 48109

Dear Dr. Eagle:

The Board of the Michigan Society of Thoracic and Cardiovascular Surgeons recently discussed the meetings of the Angioplasty SAC. We recognize the complex realities of this issue and appreciate the opportunity to provide comments.

As your committee is aware there are data describing the modest improvement in geographic access when primary PCI was expanded to hospitals in Michigan without onsite cardiac surgery.¹ One could certainly infer that access for elective PCI in the state of Michigan is excellent.

As you may know as well, there are CHRT data² for angiography, PCI, and coronary artery bypass in the state of Michigan noting significant regional variation that currently occurs in our state. One could conclude from these data that we have significant variation in approaches and procedures at major centers currently and increasing centers could further challenge our understanding of appropriate approaches to patients with ischemic heart disease. With this background, our Society believes that the SAC discussion should be a very broad one.

On March 5 there was a meeting of Cardiac Surgeons and Interventional Cardiologists representing the statewide MSTCVS Quality Collaborative and the BMC² Quality Collaborative. The purpose of this all day meeting was to review approaches to ischemic heart disease patients ranging from optimal medical therapy to percutaneous approaches, as well as operative approaches. These discussions generated the concept of a "heart team" format for patients with ischemic heart disease at hospitals in Michigan. The concept of a "heart team" recognizes the importance of communication between the various specialists that deal with ischemic heart disease patients creating collaborative decision making to provide optimal care for the patients. Approval of PCI without site Cardiac Surgery challenges these collaborative, thoughtful approaches.

On the national level, as you know, there has been considerable discussion about collaboration as well as improved "informed consent" for patients and our Society believes that a broad review and discussion of a patient's presentation and the amount of ischemia and anatomy is both appropriate and provides a balanced discussion. The recently published European "Guidelines on Myocardial revascularization"³ which we believe are excellent, specifically note that surgical

consultation should be obtained prior to PCI. Furthermore, recent analysis of CMS billing data confirms that PCI volume has begun to decrease, challenging the rationale for creating more access.⁴

There is an opportunity in Michigan to lead the country in approaching patients with cardiac disease in a collaborative fashion offering the optimal approach to all our citizens. As you know, we are creating the ability with our statewide databases to follow patients long-term and create longitudinal follow-up of outcomes with different approaches that are utilized.

It is our belief that the incentive to provide optimal care should be the driving force for thoughtful decision-making in this complex arena and we believe our state has the unique opportunity with our collaboratives to do just that in Michigan.

We appreciate the opportunity to provide our thoughts.

Sincerely,

A handwritten signature in black ink that reads "Eric J. Hanson MD". The signature is written in a cursive style.

Eric Hanson, M.D.
President,
Michigan Society of Thoracic and Cardiovascular Surgeons

¹ Buckey JW, Bates ER, Nallamothu BK. Primary percutaneous coronary intervention expansion to hospitals without on-site cardiac surgery in Michigan: a geographic information systems analysis. *Am Heart J.* 2008 Apr; 155(4): 668-72. Epub 2008 Mar 7.

² Center for Health Care Research and Transformation CHRT book, 2010.

³ *Eur J Cardiothorac Surg* 2010;38:S1-S52

⁴ Riley, R, et. al. Trends in coronary revascularization in the United States from 2001-2009. *Circ: Cardiovascular Quality Outcomes*, March 2011; 193-197.

CCSAC SURVEY SUMMARY

If the CON Commission enacts changes in the regulations surrounding the requirement for onsite cardiac surgery back-up for elective coronary PCI as outlined by the document submitted by this committee, the effect on the important domains of coronary care for Michigan's citizens will be:

Domain	Increases	Neutral	Decreases
Quality of Care	XXXXX XX	XXXX	XXXXX XXX
Access to Care	XXXXX XXXXX XXX	XXXXX X	
Cost of Care	XXXXX XXXXX X	XX	XXXXX X
Safety of Care	XXXXX XX	XXXXX X	XXXXX X
Appropriateness of Care	XXXXX X	XXXXX	XXXXX XXX

The overall financial effect that this change would likely have on the institution that I work for (or receive care at) is likely to be:

Favorable	Neutral	Unfavorable
XXX	XXXXX XXXXX XX	XXXX

Comments that I would like conveyed to the CON Commission pertaining to this recommendation include:

- 1) No practical upside for citizens of MI. Only potential downside results: higher costs, lower quality, no change in access. Likely to promote hospital/hospital system "arms race" with expenditure of resources ultimately passed on to purchaser of health care (MI citizens & employees) with no improvement in access or quality. Increase prevalence of low volume physician operators and/or inappropriate utilization. (May also apply to facilities.) Proposed quality oversight so complex and burdensome will increase costs and State likely not able to enforce. (Goodman)
- 2) My concern is opening the door to several more sites with a population decreasing which will drive cost up overall with new labs being constructed w/o demonstrated need because the procedure makes money for the hospital. Access may increase but serious questions on quality were not resolved to my satisfaction. Reality is that an increase in "cherry picking" will drive down patients going to established qualified sites. (Wells)
- 3) No issue with regards to technical safety. Increases cost. No problem with access. Risk of increasing inappropriateness of users - volume based, not quality based. "Consent bias" by not having CT surgical input on high risk cases. State will not have the resources to assure regulatory compliance, high quality expectations. Decreases volumes/skills expertise of existing close by hospitals. Increase competition around volume, not quality. (Riba)
- 4) Enforcing quality standards is critical to ensuring that quality of care and safety of care is not negatively impacted by the changes recommended. (Sottile)
- 5) Access appears to be an issue only in the Alpena area, other areas of state are well covered with current PCI programs based on population distribution. Opens the door for inappropriate PCI to meet and maintain volume requirements. Given the trend of decreasing PCI volumes nationally, programs would just be shifting volumes between sites. May increase costs across the overall system of care. Revocation of CON language needed in standards for elective PCI w/o OHS. (Berndt)
- 6) The expansion of programs to perform PCI without OHS should allow an expansion of medical technology to less costly venues which should mitigate any increased costs due to an expansion of programs. The performance and quality requirements should maintain or enhance quality. (Palmer)
- 7) Evidence based to do PCI w/o OHS. Unless all diagnostics labs close, we will continue to do dx-caths and have to transfer patients for PCI, inconvenient for patients - increase cost. No need to multiple low-volume CABG centers. Critical importance that this be regulated and enforced based on our proposed criteria.
- 8) This allows increased access for therapeutic PCI, enhances quality, decreases cost of care, enhances safety, and enhances appropriateness. This puts MI in better position to benchmark off the work in other states with respect to PCI services for its citizens. I am in full support of the recommended changes. (Buxton)

- 9) Absolutely need the ability to revoke an organization's CON if it does not meet volume, quality requirements. Does not address the needs of the 20% underserved within the state. Is not currently supported by the ACC.
- 10) Moving in this way makes us consistent with practice in the US (43 states) and most western countries outside the US. It increases access, it keeps continuity of care (people stay in system within their location). It will decrease the cost of care - there will be no need for more surgical programs and some that currently exist will close. PCI is an everyday procedure and patients want it done in their usual hospital; this will increase value by improving access and reducing cost. There are many patients who belong to large health care systems with high quality - producing the ability to keep their patients with their regular doctor will lead to higher quality, patient-centered care. (Weaver)
- 11) Sufficient evidence was presented that performing elective PCI without on-site open heart back-up is safe and more easier for the citizens of MI provided that quality is outlined in standards and are enforced. (Ashkar)
- 12) Major concern that we are not really increasing access because of close proximity to sites that already provide these services, but could also be decreasing quality outcomes by diluting volume numbers at existing sites. I also believe that while we added language to address quality that due to limited resources by the state or another 3rd party - we will not really have a way to monitor those. (Raica)
- 13) I am very concerned about expanding this service without the state Commission's buy in that programs will have their CON revoked if not compliant.
- 14) No access to care issues. This proposal would decrease volume at existing programs and shift volume with increase costs to newer programs. (Dobies)
- 15) Overall an educational, challenging, and rewarding experience evaluating all aspects of this issue. In doing so, I feel that the key components have been addressed including safety, access, and appropriateness, and in the end, the citizens of MI will be better served because of this. However, this is something that will require continuous review and updating, and will undoubtedly require a re-convening of a SAC in the not too distant future, possibly on a regular basis. (Lewis)
- 16) I do not think that access is improved and remain very concerned that total safety will be jeopardized. I think it is difficult to control or regulate unintended problems that I think are likely to occur.
- 17) This should drastically reduce cost of care by requiring small volume open heart programs to close. By increasing public transparency, quality will improve. Local access and convenience to the individual citizen will also increase provided that tight enforcement rewards, overall safety will increase. (Schreiber)
- 18) Decoupling of elective PCI is not necessary. This change will likely add cost, potentially reducing quality, but encouraging inappropriate PCIs. If the state does not carefully regulate this clinical area, including decredentialing labs and operators that do not meet volume and quality standards, the potential to harm MI residents is great. (Eagle)
- 19) Better access. Lets market dictate need. (Donovan)

CERTIFICATE OF NEED REVIEW STANDARDS FOR CARDIAC
CATHETERIZATION (CC) SERVICES
SUMMARY OF PROPOSED CHANGES

Highlights of Proposed Changes

Section 1- Applicability

- Section 1 modified only for consistency with other CON review standards.

Section 2- Definitions

- The definitions that pertain only to a certain section have been moved to that section to make it easier for the reader to identify the defined terms.
- Eliminated definitions that are no longer needed.
- Clarified definitions.
- Modified definition for cardiac catheterization procedure to exclude the implantation of cardiac permanent pacemakers and implantable cardioverter defibrillators (ICD) devices that are performed in an interventional radiology laboratory or operating room.
- Added new definition for elective PCI.
- Modified definition for therapeutic cardiac catheterization service to include transcatheter valves, other structural heart disease procedures, and left sided arrhythmia procedures.

Section 3- Initiation of Cardiac Catheterization Service

- Sections 3, 4, 5, 6, and 7 were combined as these sections related to the initiation of a CC service.
- Section modified for consistency within review standards for initiation of CC services.
- Subsection 4 was modified to reflect the SACs recommendation of the minimum 500 procedure equivalents to initiate, in which 400 must be within the category of CC procedures. Projection procedures for initiation of primary PCI decreased from 48 to 36.
- Added subsection 5 outlining requirements to initiate elective PCI without on-site open heart surgery services.
- Annual maintenance volume requirements have been moved to the project delivery requirements.

Section 4- Replace Existing Cardiac Catheterization Service or Laboratory

- The replacement section will cover both the replacement of the laboratory and equipment as well as replacing the existing service to a new geographical site as part of replacing the entire hospital.
- Replacement of a laboratory or equipment will no longer require the applicant to meet set volume requirements. Upgrades to existing CC services, without replacement of the laboratory or equipment will not require CON review/approval.
- Further clarification of replacement definition as it applies to CC laboratories and relocation of CC service to a new site.

Section 5- Expand a Cardiac Catheterization Service

- The Department eliminated the requirement to project procedure equivalents.
- The Department modified the volume requirement for existing and approved laboratories to include the SAC's recommendation of 1,400 procedure equivalents, and minimum threshold must be met in each applicable service category.

Section 6- Acquire a Cardiac Catheterization Service

- Added language for acquisition consistent with other CON review standards which includes the following:
 - Acquisition of CC services as part of the overall acquisition of a hospital.
 - Renewal of lease for angiography x-ray equipment without volume requirements.

Section 7- Medicaid Participation

- No changes proposed. Modification to section is to standardize language similar to other standards on Medicaid participation requirement.

Section 8- Project Delivery Requirements

- Divided requirements into distinct groups: quality assurance, access to care, monitoring and reporting, and specialized services.
- Annual volume requirements have been moved to the applicable project delivery requirements subsection.
- Added project delivery requirements for elective PCI without on-site open heart surgery services.

Section 9- Methodology for Computing Cardiac Catheterization Equivalents

- The Department deleted language under the previous Section 11(2) to allow for the counting of peripheral catheterizations under expansion. Further, due to elimination of volume requirements for replacement, this language is no longer necessary.
- The Department modified the procedures and weight equivalents to reflect the SAC's recommendations.

Section 10- Documentation of Projections

- The Department modified the language to reflect the minimum projected volume requirement from 48 to 36 ST segment elevation AMI cases for primary PCI services.
- The Department modified the language to reflect the addition of elective PCI services.

Section 11- Comparative Reviews and Planning Policies

- No changes proposed, except updated effective dates.

Addition of Health Services Areas - Appendix A

- Added to facilitate modifications within PCI requirements.

Current Appendix B

- Moved from previous Appendix A (identification of rural, micropolitan, and metropolitan statistical area counties).

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR CARDIAC CATHETERIZATION SERVICES

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

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval OF THE INITIATION, REPLACEMENT, EXPANSION, OR ACQUISITION OF CARDIAC CATHETERIZATION SERVICES, and THE delivery of THESE services under Part 222 of the Code. PURSUANT TO PART 222 OF THE CODE, cardiac catheterization services are A covered clinical service. The Department shall use THESE STANDARDS in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws AND Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

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

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

(B) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, performed on a patient during a single session in a laboratory. Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aides in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart. THIS TERM DOES not include "float catheters" THAT are performed at the bedside or in settings outside the laboratory OR THE IMPLANTATION OF CARDIAC PERMANENT PACEMAKERS AND IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICD) DEVICES THAT ARE PERFORMED IN AN INTERVENTIONAL RADIOLOGY LABORATORY OR OPERATING ROOM.

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

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

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

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

(G) "Diagnostic cardiac catheterization service" means providing diagnostic cardiac catheterization PROCEDURES on an organized, regular basis in a laboratory TO DIAGNOSE ANATOMICAL AND/OR PHYSIOLOGICAL PROBLEMS IN THE HEART. PROCEDURES include the intra coronary administration of drugs; left heart catheterization; right heart catheterization; coronary angiography; diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic). A hospital that provides pediatric diagnostic cardiac catheterization services MAY ALSO PERFORM BALLOON ATRIAL SEPTOSTOMY PROCEDURES. A hospital that PROVIDES DIAGNOSTIC cardiac catheterization

53 services MAY ALSO PERFORM IMPLANTATIONS OF CARDIAC PERMANENT PACEMAKERS AND
54 ICD DEVICES.

55 (H) "ELECTIVE PERCUTANEOUS CORONARY INTERVENTION (PCI) SERVICE" MEANS
56 PROVIDING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND
57 CORONARY STENT IMPLANTATION ON AN ORGANIZED, REGULAR BASIS IN A LABORATORY AT
58 A HOSPITAL WITHOUT ON-SITE OPEN HEART SURGICAL SERVICES. THE TERM DOES NOT
59 INCLUDE TRANSCATHETER VALVE, OTHER STRUCTURAL HEART DISEASE PROCEDURES, OR
60 LEFT SIDED ARRHYTHMIA THERAPEUTIC PROCEDURES. A HOSPITAL THAT PROVIDES
61 ELECTIVE PCI SERVICES MAY ALSO PERFORM IMPLANTATIONS OF CARDIAC PERMANENT
62 PACEMAKERS, ICD DEVICES, AND RIGHT SIDED CATHETER ABLATION PROCEDURES.
63 STRUCTURAL HEART DISEASE PROCEDURES CAN ONLY BE PERFORMED WITHIN A HOSPITAL
64 THAT HAS ON-SITE OPEN HEART SURGICAL SERVICES.

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

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

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

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

74 (M) "Pediatric cardiac catheterization service" means PROVIDING cardiac catheterization services on
75 an organized, regular basis to infants and children ages 18 and below, except for electrophysiology
76 studies THAT are offered and provided to infants and children ages 14 and below, and others with
77 congenital heart disease as defined by the ICD-9-CM codes of 426.7 (ANOMALOUS
78 ATRIOVENTRICULAR EXCITATION), 427.0 (CARDIAC DYSRHYTHMIAS), and 745.0 through 747.99
79 (BULBUS CORDIS ANOMALIES AND ANOMALIES OF CARDIAC SEPTAL CLOSURE, OTHER
80 CONGENITAL ANOMALIES OF HEART, AND OTHER CONGENITAL ANOMALIES OF CIRCULATORY
81 SYSTEM).

82 (N) "Primary PCI" means a PCI performed ON AN acute myocardial infarction (AMI) patient with
83 confirmed ST elevation or new left bundle branch block.

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

86 (P) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac
87 catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or
88 physiological problems in the heart. PROCEDURES include PCI, PTCA, atherectomy, stent, laser,
89 cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD
90 device implantations, TRANSCATHETER VALVE, OTHER STRUCTURAL HEART DISEASE
91 PROCEDURES, AND LEFT SIDED ARRHYTHMIA THERAPEUTIC PROCEDURES. The term does
92 not include the intra coronary administration of drugs where that is the only therapeutic intervention.

93
94 (2) Terms defined in the Code have the same meanings when used in these standards.
95

96 **Section 3. Requirements to initiate cardiac catheterization services**

97
98 Sec. 3. AN APPLICANT PROPOSING TO INITIATE CARDIAC CATHETERIZATION SERVICES
99 SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.

100
101 (1) An applicant proposing to initiate an adult diagnostic cardiac catheterization service shall
102 DEMONSTRATE the following, as applicable TO THE PROPOSED PROJECT:

103 (A) THE APPLICANT IS APPLYING TO INITIATE PRIMARY PCI, ELECTIVE PCI, OR
104 THERAPEUTIC CARDIAC CATHETERIZATION SERVICES.

105 (B) THE APPLICANT SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE
106 PROPOSED PROJECT:

107 (I) AN APPLICANT PROPOSING TO INITIATE WITH A SINGLE LABORATORY IN A rural or
108 micropolitan statistical area county SHALL PROJECT a minimum of 500 procedure equivalents including
109 300 procedure equivalents in the category of diagnostic cardiac catheterization PROCEDURES BASED
110 ON DATA FROM THE MOST RECENT 12-MONTH PERIOD PRECEDING THE DATE THE
111 APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

112 (II) AN APPLICANT PROPOSING TO INITIATE WITH A SINGLE LABORATORY in a metropolitan
113 statistical area county SHALL PROJECT a minimum of 750 procedure equivalents THAT includes 300
114 procedure equivalents in the category of diagnostic cardiac catheterization PROCEDURES BASED ON
115 DATA FROM THE MOST RECENT 12-MONTH PERIOD PRECEDING THE DATE THE APPLICATION
116 WAS SUBMITTED TO THE DEPARTMENT.

117 (III) An applicant proposing to initiate WITH TWO or more laboratories shall project a minimum of
118 1,000 procedure equivalents per laboratory THAT INCLUDES 300 PROCEDURE EQUIVALENTS IN THE
119 CATEGORY OF DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES BASED ON DATA
120 FROM THE MOST RECENT 12-month PERIOD PRECEDING THE DATE THE APPLICATION WAS
121 SUBMITTED TO THE DEPARTMENT.

122
123 (2) An applicant proposing to INITIATE AN ADULT therapeutic cardiac catheterization SERVICE
124 shall demonstrate the following:

125 (a) THE applicant provides, IS APPROVED TO PROVIDE, or has APPLIED to provide adult
126 diagnostic cardiac catheterization services AT THE HOSPITAL. THE APPLICANT MUST BE
127 APPROVED FOR ADULT DIAGNOSTIC CARDIAC CATHETERIZATION SERVICES IN ORDER TO BE
128 APPROVED FOR ADULT THERAPEUTIC CARDIAC CATHETERIZATION SERVICES.

129 (b) AN APPLICANT OPERATING AN ADULT DIAGNOSTIC CARDIAC CATHETERIZATION
130 SERVICE HAS PERFORMED A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY
131 OF ADULT DIAGNOSTIC CARDIAC CATHETERIZATIONS DURING THE MOST RECENT 12-MONTH
132 PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT IF
133 THE SERVICE HAS BEEN IN OPERATION MORE THAN 24 MONTHS.

134 (C) THE applicant HAS APPLIED TO provide adult open heart surgery services AT the hospital. The
135 APPLICANT MUST BE APPROVED FOR AN ADULT OPEN HEART SURGERY SERVICE IN ORDER
136 TO BE APPROVED FOR AN ADULT therapeutic cardiac catheterization SERVICE.

137 (D) THE applicant shall project a minimum of 300 procedure equivalents in the category of adult
138 therapeutic cardiac catheterizations BASED ON DATA FROM THE MOST RECENT 12-MONTH PERIOD
139 PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

140
141 (3) An applicant proposing to initiate a pediatric cardiac catheterization service SHALL
142 DEMONSTRATE THE FOLLOWING:

143 (A) THE APPLICANT HAS A board certified pediatric cardiologist with training in pediatric
144 catheterization procedures to direct the pediatric catheterization laboratory.

145 (B) THE APPLICANT HAS standardized equipment as DEFINED IN THE MOST CURRENT
146 AMERICAN ACADEMY OF PEDIATRICS (AAP) Guidelines FOR PEDIATRIC CARDIOVASCULAR
147 CENTERS.

148 (C) THE APPLICANT HAS on-site ICU as outlined in THE MOST CURRENT AAP guidelines
149 ABOVE.

150 (D) THE APPLICANT HAS APPLIED TO PROVIDE pediatric open heart surgery SERVICES AT THE
151 HOSPITAL. THE APPLICANT MUST BE APPROVED FOR A PEDIATRIC OPEN HEART SURGERY
152 SERVICE IN ORDER TO BE APPROVED FOR PEDIATRIC CARDIAC CATHETERIZATION SERVICES.

153 (E) THE applicant shall project a minimum of 600 procedure equivalents in the category of pediatric
154 cardiac catheterizations BASED ON DATA FROM THE MOST RECENT 12-MONTH PERIOD
155 PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

156

- 157 (4) An applicant proposing to initiate primary PCI service without on-site open heart surgery services
158 shall demonstrate the following:
- 159 (a) The applicant OPERATES AN adult diagnostic cardiac catheterization service THAT HAS
160 performed a minimum of 500 procedure EQUIVALENTS THAT INCLUDES 400 PROCEDURE
161 EQUIVALENTS IN THE CATEGORY OF CARDIAC CATHETERIZATION PROCEDURES during the
162 most recent 12 months preceding the date the application was submitted to the Department.
- 163 (b) The APPLICANT HAS AT LEAST TWO interventional cardiologists to perform the primary PCI
164 PROCEDURES AND EACH CARDIOLOGIST HAS performed at least 75 PCI SESSIONS annually as the
165 primary operator during the most recent 24-month PERIOD preceding the date the application was
166 submitted to the Department.
- 167 (c) The nursing and technical catheterization laboratory staff: are experienced in handling acutely ill
168 patients and comfortable with interventional equipment; have acquired experience in dedicated
169 interventional laboratories at an open heart surgery HOSPITAL; and participate in an un-interrupted 24-
170 hour, 365-day call schedule. Competency SHALL be documented annually.
- 171 (d) The laboratory OR LABORATORIES ARE equipped with optimal imaging systems, resuscitative
172 equipment, AND intra-aortic balloon pump (IABP) support, and stocked with a broad array of
173 interventional equipment.
- 174 (e) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management.
175 Competency SHALL be documented annually.
- 176 (f) A written agreement with an open heart surgery HOSPITAL that includes ALL OF THE
177 FOLLOWING:
- 178 (i) Involvement in credentialing criteria and recommendations for physicians approved to perform
179 primary PCI PROCEDURES.
- 180 (ii) Provision for ongoing cross-training for professional and technical staff involved in the provision of
181 primary PCI to ensure familiarity with interventional equipment. Competency SHALL be documented
182 annually.
- 183 (iii) Provision for ongoing cross training for emergency department, catheterization laboratory, and
184 critical care unit staff to ensure experience in handling the high acuity status of primary PCI patient
185 candidates. Competency SHALL be documented annually.
- 186 (iv) Regularly held joint cardiology/cardiac surgery conferences to include review of all primary PCI
187 cases.
- 188 (v) Development and ongoing review of patient selection criteria for primary PCI patients and
189 implementation of those criteria.
- 190 (vi) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for
191 prompt care.
- 192 (vii) Written protocols, signed by the applicant and the open heart surgery HOSPITAL, for the
193 immediate transfer, within 1 hour from THE cardiac catheterization laboratory to evaluation on site in the
194 open heart surgery HOSPITAL, of patients requiring surgical evaluation and/or intervention 365 days a
195 year. The protocols shall be reviewed AND tested on a quarterly basis.
- 196 (viii) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for
197 the provision of interventional procedures.
- 198 (g) A written protocol must be established and maintained for case selection for the performance of
199 primary PCI.
- 200 (h) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid
201 transfer from the emergency department to the CARDIAC catheterization laboratory must be developed
202 and maintained so that door-to-balloon targets are met.
- 203 (i) At least two physicians credentialed to perform primary PCI must commit to functioning as a
204 coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day
205 per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying
206 the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate
207 with administrative and clinical staff in establishing and implementing protocols, call schedules, and
208 quality assurance procedures pertaining to primary PCI designed to meet the requirements for this
209 certification and in keeping with the current guidelines for the provision of primary PCI promulgated by the
210 American College of Cardiology and American Heart Association.

211 (J) THE applicant shall project a minimum of 36 primary PCI CASES BASED ON DATA FROM THE
212 MOST RECENT 12-month PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO
213 THE DEPARTMENT.
214

215 (5) AN APPLICANT PROPOSING TO INITIATE AN ELECTIVE PCI SERVICE WITHOUT ON-SITE
216 OPEN HEART SURGERY SERVICES SHALL DEMONSTRATE THE FOLLOWING:

217 (A) THE APPLICANT PROVIDES, IS APPROVED TO PROVIDE, OR HAS APPLIED TO PROVIDE
218 ADULT DIAGNOSTIC CARDIAC CATHETERIZATION SERVICES AT THE HOSPITAL. THE
219 APPLICANT MUST BE APPROVED FOR ADULT DIAGNOSTIC CARDIAC CATHETERIZATION
220 SERVICES IN ORDER TO BE APPROVED FOR ELECTIVE PCI SERVICES.

221 (B) THE APPLICANT HAS AT LEAST TWO INTERVENTIONAL CARDIOLOGISTS TO PERFORM
222 PCI PROCEDURES AT THE HOSPITAL THAT MEET THE FOLLOWING:

223 (I) BOARD CERTIFIED IN INTERVENTIONAL CARDIOLOGY.

224 (II) INDIVIDUAL OUTCOMES ARE COMPARABLE TO NATIONAL OUTCOMES.

225 (III) PERFORMED AT LEAST 300 PCI SESSIONS SINCE FELLOWSHIP.

226 (IV) PERFORMED AT LEAST 100 PCI SESSIONS DURING THE MOST RECENT 24-MONTH
227 PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

228 (C) A WRITTEN AGREEMENT WITH AN OPEN HEART SURGERY HOSPITAL THAT INCLUDES:

229 (I) SIGNATURES BY SENIOR EXECUTIVES FROM THE APPLICANT HOSPITAL AND THE
230 HOSPITAL WITH OPEN HEART SURGERY SERVICES.

231 (II) INVOLVEMENT IN THE CREDENTIALING CRITERIA AND RECOMMENDATIONS FOR
232 PHYSICIANS APPROVED TO PERFORM PCI.

233 (III) PROVISION FOR ONGOING CROSS-TRAINING FOR PROFESSIONAL AND TECHNICAL
234 STAFF INVOLVED IN THE PROVISION OF PCI TO ENSURE FAMILIARITY WITH INTERVENTIONAL
235 EQUIPMENT. COMPETENCY SHALL BE DOCUMENTED ANNUALLY.

236 (IV) PROVISION FOR ONGOING CROSS TRAINING FOR EMERGENCY DEPARTMENT,
237 CATHETERIZATION LABORATORY AND CRITICAL CARE UNIT STAFF TO ENSURE EXPERIENCE
238 IN HANDLING THE HIGH ACUITY STATUS OF PCI PATIENT CANDIDATES. COMPETENCY SHALL
239 BE DOCUMENTED ANNUALLY.

240 (V) REGULARLY HELD JOINT CARDIOLOGY/CARDIAC SURGERY CONFERENCES (AT LEAST
241 QUARTERLY) TO INCLUDE REVIEW OF ALL PCI CASES AND OUTCOMES;

242 (VI) DEVELOPMENT AND ONGOING REVIEW OF PATIENT SELECTION CRITERIA FOR PCI
243 PATIENTS AND IMPLEMENTATION OF THOSE CRITERIA.

244 (VII) A MECHANISM TO PROVIDE FOR APPROPRIATE PATIENT TRANSFERS BETWEEN
245 HOSPITALS AND AN AGREED PLAN FOR PROMPT CARE; WRITTEN PROTOCOLS, SIGNED BY
246 THE APPLICANT AND THE OPEN HEART SURGICAL HOSPITAL, MUST BE IN PLACE WITH
247 PROVISIONS FOR IMMEDIATE AND EFFICIENT TRANSFER WITHIN ONE HOUR OF PATIENTS
248 REQUIRING SURGICAL EVALUATION AND/OR INTERVENTION 24 HOURS PER DAY, 365 DAYS A
249 YEAR. THE PROTOCOLS SHALL BE REVIEWED/TESTED ON A REGULAR, SEMI-ANNUAL BASIS.

250 (VIII) ABILITY TO TRANSFER IMAGES ELECTRONICALLY FOR THE CONCURRENT REVIEW OF
251 CASES WITH THE OPEN HEART SURGERY HOSPITAL IF NEEDED.

252 (IX) CONSULTATION ON FACILITIES, EQUIPMENT, STAFFING, ANCILLARY SERVICES, AND
253 POLICIES AND PROCEDURES FOR THE PROVISION OF INTERVENTIONAL PROCEDURES.

254 (D) THE APPLICANT AGREES TO THE FOLLOWING:

255 (I) A WRITTEN PROTOCOL MUST BE ESTABLISHED AND MAINTAINED FOR CASE
256 SELECTION FOR THE PERFORMANCE OF PCI THAT IS CONSISTENT WITH CURRENT PRACTICE
257 GUIDELINES SET FORTH BY THE AMERICAN COLLEGE OF CARDIOLOGY AND THE AMERICAN
258 HEART ASSOCIATION, INCLUDING A RISK STRATIFICATION TOOL (STS OR SYNTAX) USED AND
259 RECORDED TO INSURE APPROPRIATE TRIAGE TO CORONARY ARTERY BYPASS GRAFT
260 SURGERY. EXCLUSIONS FOR ELECTIVE PCI SHOULD INCLUDE DECOMPENSATED HEART
261 FAILURE WITHOUT ACUTE ISCHEMIA, RECENT STROKE, ADVANCED MALIGNANCY, KNOWN
262 CLOTTING DISORDERS, EF LESS THAN 25%, LEFT MAIN DISEASE UNPROTECTED BY PRIOR
263 SURGERY, LESIONS THAT JEOPARDIZE >50% OF MYOCARDIUM, DIFFUSE DISEASE AND

264 EXCESSIVE TORTUOSITY, DEGENERATED VEIN GRAFTS, SUBSTANTIAL THROMBUS,
 265 AGGRESSIVE MEASURES TO OPEN CHRONIC TOTAL OCCLUSIONS, AND INABILITY TO
 266 PROTECT MAJOR SIDE BRANCHES.

267 (II) ESTABLISH AND MAINTAIN WRITTEN POLICY AND PROCEDURES FOR TRAINING,
 268 STAFFING, AND PROGRAM REVIEW.

269 (III) THE NURSING AND TECHNICAL CATHETERIZATION STAFF ARE EXPERIENCED IN
 270 HANDLING ACUTELY ILL PATIENTS AND COMFORTABLE WITH INTERVENTIONAL EQUIPMENT;
 271 HAVE ACQUIRED EXPERIENCE IN DEDICATED INTERVENTIONAL LABORATORIES AT OPEN
 272 HEART SURGERY SERVICES OR AT PRIMARY PCI SERVICES; AND PARTICIPATE IN AN UN-
 273 INTERRUPTED 24-HOUR, 365-DAY CALL SCHEDULE. COMPETENCY SHALL BE DOCUMENTED
 274 ANNUALLY.

275 (IV) THE CATHETERIZATION LABORATORY IS EQUIPPED WITH IMAGING SYSTEMS,
 276 RESUSCITATIVE EQUIPMENT, INTRA-AORTIC BALLOON PUMP (IABP) SUPPORT, AND STOCKED
 277 WITH APPROPRIATE INTERVENTIONAL EQUIPMENT.

278 (V) THE CARDIAC CARE UNIT NURSES ARE ADEPT IN HEMODYNAMIC MONITORING AND
 279 IABP MANAGEMENT. COMPETENCY SHALL BE DOCUMENTED ANNUALLY.

280 (VI) ESTABLISH AND MAINTAIN A SYSTEM TO ENSURE PROMPT AND EFFICIENT
 281 IDENTIFICATION OF POTENTIAL PRIMARY PCI PATIENTS AND RAPID TRANSFER TO THE
 282 CATHETERIZATION LABORATORY SO THAT DOOR-TO-BALLOON TARGETS ARE MET.

283 (VII) AT LEAST TWO PHYSICIANS CREDENTIALLED TO PERFORM PRIMARY PCI MUST COMMIT
 284 TO FUNCTIONING AS A COORDINATED GROUP WILLING AND ABLE TO PROVIDE THIS SERVICE
 285 AT THE HOSPITAL ON A 24-HOUR PER DAY, 365 DAY PER YEAR CALL SCHEDULE, WITH ABILITY
 286 TO BE ON-SITE AND AVAILABLE TO OPERATE WITHIN 30 MINUTES OF IDENTIFYING THE NEED
 287 FOR PRIMARY PCI. THESE PHYSICIANS MUST BE CREDENTIALLED AT THE FACILITY AND
 288 ACTIVELY COLLABORATE WITH ADMINISTRATIVE AND CLINICAL STAFF IN ESTABLISHING AND
 289 IMPLEMENTING PROTOCOLS, CALL SCHEDULES, AND QUALITY ASSURANCE PROCEDURES
 290 PERTAINING TO PRIMARY PCI DESIGNED TO MEET THE REQUIREMENTS FOR THIS
 291 CERTIFICATION AND IN KEEPING WITH THE CURRENT GUIDELINES FOR THE PROVISION OF
 292 PRIMARY PCI PROMULGATED BY THE AMERICAN COLLEGE OF CARDIOLOGY AND AMERICAN
 293 HEART ASSOCIATION.

294 (E) THE APPLICANT SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE
 295 PROPOSED PROJECT:

296 (I) AN APPLICANT WITHIN ONE HOUR DRIVE TIME OF AN EXISTING PCI OR OPEN HEART
 297 SURGERY HOSPITAL SHALL PROJECT A MINIMUM OF 350 PCI (PTCA AND CORONARY STENT)
 298 CASES BASED ON DATA FROM THE MOST RECENT 12-MONTH PERIOD PRECEDING THE DATE
 299 THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT. THE DEPARTMENT SHALL REVOKE
 300 A CON FOR A PROGRAM THAT PERFORMS LESS THAN 250 PCIS IN THE SECOND 12 MONTHS
 301 OF OPERATION, OR LESS THAN 350 PCIS IN THE THIRD 12 MONTHS OF OPERATION, AND/OR IS
 302 RECOMMENDED FOR REVOCATION BY THE ORGANIZATION IDENTIFIED IN SECTION 8(6)(C).

303 (II) AN APPLICANT MORE THAN ONE HOUR DRIVE TIME OF AN EXISTING PCI OR OPEN
 304 HEART SURGERY HOSPITAL SHALL PROJECT A MINIMUM OF 250 PCI (PTCA AND CORONARY
 305 STENT) CASES BASED ON DATA FROM THE MOST RECENT 12-MONTH PERIOD PRECEDING THE
 306 DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT. THE DEPARTMENT SHALL
 307 REVOKE A CON FOR A PROGRAM THAT PERFORMS LESS THAN 250 PCIS IN THE THIRD 12
 308 MONTHS OF OPERATIONS AND/OR IS RECOMMENDED FOR REVOCATION BY THE
 309 ORGANIZATION IDENTIFIED IN SECTION 8(6)(C).

310
 311 **Section 4. Requirements to replace AN EXISTING cardiac catheterization SERVICE OR laboratory**
 312

313 Sec. 4. REPLACING A CARDIAC CATHETERIZATION LABORATORY MEANS A CHANGE IN THE
 314 ANGIOGRAPHY X-RAY EQUIPMENT OR A RELOCATION OF THE SERVICE TO A NEW SITE. THE
 315 TERM DOES NOT INCLUDE A CHANGE IN ANY OF THE OTHER EQUIPMENT OR SOFTWARE
 316 USED IN THE LABORATORY. AN APPLICANT PROPOSING TO REPLACE A CARDIAC

317 CATHETERIZATION LABORATORY OR SERVICE SHALL DEMONSTRATE THE FOLLOWING, AS
 318 APPLICABLE TO THE PROPOSED PROJECT:

319 (1) AN APPLICANT PROPOSING TO REPLACE CARDIAC CATHETERIZATION LABORATORY
 320 EQUIPMENT SHALL DEMONSTRATE THE FOLLOWING:

321 (A) THE EXISTING LABORATORY OR LABORATORIES TO BE REPLACED ARE FULLY
 322 DEPRECIATED ACCORDING TO GENERALLY ACCEPTED ACCOUNTING PRINCIPLES OR
 323 DEMONSTRATES EITHER OF THE FOLLOWING:

324 (i) THE EXISTING ANGIOGRAPHY X-RAY EQUIPMENT TO BE REPLACED POSES A THREAT
 325 TO THE SAFETY OF THE PATIENTS.

326 (ii) THE REPLACEMENT ANGIOGRAPHY X-RAY EQUIPMENT OFFERS TECHNOLOGICAL
 327 IMPROVEMENTS THAT ENHANCE QUALITY OF CARE, INCREASES EFFICIENCY, AND REDUCES
 328 OPERATING COSTS.

329 (B) THE EXISTING ANGIOGRAPHY X-RAY EQUIPMENT TO BE REPLACED WILL BE REMOVED
 330 FROM SERVICE ON OR BEFORE BEGINNING OPERATION OF THE REPLACEMENT EQUIPMENT.

331
 332 (2) An applicant PROPOSING TO REPLACE A cardiac catheterization service TO A NEW SITE
 333 SHALL DEMONSTRATE the following:

334 (a) THE PROPOSED PROJECT IS PART OF AN APPLICATION TO REPLACE THE ENTIRE
 335 HOSPITAL.

336 (b) THE APPLICANT HAS PERFORMED THE FOLLOWING DURING THE MOST RECENT 12-
 337 MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE
 338 DEPARTMENT, AS APPLICABLE TO THE PROPOSED PROJECT:

339 (i) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT
 340 DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES.

341 (ii) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT
 342 THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES.

343 (iii) A MINIMUM OF 600 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PEDIATRIC
 344 CARDIAC CATHETERIZATION PROCEDURES.

345 (iv) A MINIMUM OF 500 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A RURAL OR
 346 MICROPOLITAN COUNTY WITH ONE LABORATORY.

347 (v) A MINIMUM OF 750 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A METROPOLITAN
 348 COUNTY WITH ONE LABORATORY.

349 (vi) A MINIMUM OF 1,000 PROCEDURE EQUIVALENTS PER CARDIAC CATHETERIZATION
 350 LABORATORY FOR A HOSPITAL WITH TWO OR MORE LABORATORIES.

351 (C) THE EXISTING CARDIAC CATHETERIZATION SERVICE HAS BEEN IN OPERATION FOR AT
 352 LEAST 36 MONTHS AS OF THE DATE THE APPLICATION HAS BEEN SUBMITTED TO THE
 353 DEPARTMENT.

354

355 **Section 5. Requirements to expand a cardiac catheterization service**

356

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

359

360 (1) THE APPLICANT HAS PERFORMED THE FOLLOWING DURING THE MOST RECENT 12-
 361 MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE
 362 DEPARTMENT, AS APPLICABLE TO THE PROPOSED PROJECT:

363 (A) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT
 364 DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES.

365 (B) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT
 366 THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES.

367 (C) A MINIMUM OF 600 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PEDIATRIC
 368 CARDIAC CATHETERIZATION PROCEDURES.

369

370 (2) THE APPLICANT HAS PERFORMED A MINIMUM OF 1,400 procedure equivalents PER existing
 371 and APPROVED LABORATORIES DURING THE MOST RECENT 12-month PERIOD PRECEDING THE
 372 DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.
 373

374 **Section 6. Requirements TO ACQUIRE a cardiac catheterization SERVICE**

375
 376 Sec. 6. ACQUIRING A CARDIAC CATHETERIZATION SERVICE AND ITS LABORATORIES
 377 MEANS OBTAINING POSSESSION AND CONTROL BY CONTRACT, OWNERSHIP, LEASE OR
 378 OTHER COMPARABLE ARRANGEMENT OR RENEWAL OF A LEASE FOR EXISTING
 379 ANGIOGRAPHY X-RAY EQUIPMENT. AN APPLICANT PROPOSING TO ACQUIRE A CARDIAC
 380 CATHETERIZATION SERVICE OR RENEW A LEASE FOR EQUIPMENT SHALL DEMONSTRATE THE
 381 FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT:
 382

383 (1) AN APPLICANT PROPOSING TO ACQUIRE A CARDIAC CATHETERIZATION SERVICE
 384 SHALL DEMONSTRATE THE FOLLOWING:

385 (A) THE PROPOSED PROJECT IS PART OF AN APPLICATION TO ACQUIRE THE ENTIRE
 386 HOSPITAL.

387 (B) AN APPLICATION FOR THE FIRST ACQUISITION OF AN EXISTING CARDIAC
 388 CATHETERIZATION SERVICE AFTER <INSERT EFFECTIVE DATE OF THESE STANDARDS> SHALL
 389 NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS IN
 390 SUBDIVISION (C). THE CARDIAC CATHETERIZATION SERVICE SHALL BE OPERATING AT THE
 391 APPLICABLE VOLUMES SET FORTH IN THE PROJECT DELIVERY REQUIREMENTS IN THE
 392 SECOND 12 MONTHS OF OPERATION OF THE SERVICE BY THE APPLICANT AND ANNUALLY
 393 THEREAFTER.

394 (C) THE APPLICANT HAS PERFORMED THE FOLLOWING DURING THE MOST RECENT 12-
 395 MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE
 396 DEPARTMENT, AS APPLICABLE TO THE PROPOSED PROJECT :

397 (I) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT
 398 DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES.

399 (II) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT
 400 THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES.

401 (III) A MINIMUM OF 600 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PEDIATRIC
 402 CARDIAC CATHETERIZATION PROCEDURES.

403 (IV) A MINIMUM OF 500 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A RURAL OR
 404 MICROPOLITAN COUNTY WITH ONE LABORATORY.

405 (V) A MINIMUM OF 750 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A METROPOLITAN
 406 COUNTY WITH ONE LABORATORY.

407 (VI) A MINIMUM OF 1,000 PROCEDURE EQUIVALENTS PER CARDIAC CATHETERIZATION
 408 LABORATORY FOR TWO OR MORE LABORATORIES.
 409

410 (2) AN APPLICANT PROPOSING TO RENEW A LEASE FOR EXISTING ANGIOGRAPHY X-RAY
 411 EQUIPMENT SHALL DEMONSTRATE THE RENEWAL OF THE LEASE IS MORE COST EFFECTIVE
 412 THAN REPLACING THE EQUIPMENT.
 413

414 **Section 7. REQUIREMENT FOR MEDICAID PARTICIPATION**

415
 416 Sec. 7. An applicant shall provide verification of Medicaid participation at the time the application is
 417 submitted to the Department. An applicant that is initiating a new service or is a new provider not
 418 currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the
 419 Department within six (6) months from the offering of services if a CON is approved.

420 **Section 8. Project delivery requirements AND terms of approval for all applicants**
421

422 Sec. 8. An applicant shall agree that, if approved, the CARDIAC CATHETERIZATION SERVICE AND
423 ALL EXISTING AND APPROVED LABORATORIES shall be delivered in compliance with the following
424 terms of approval:

- 425
- 426 (1) Compliance with these standards.
- 427
- 428 (2) Compliance with the following quality assurance standards:
- 429 (A) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory
430 located within a hospital, and have within, or immediately available to the room, dedicated emergency
431 equipment to manage cardiovascular emergencies.
- 432 (B) The service shall be staffed with sufficient medical, nursing, technical and other personnel to
433 permit regular scheduled hours of operation and continuous 24-hour on-call availability.
- 434 (C) The medical staff and governing body shall receive and review at least annual reports describing
435 the activities of the cardiac catheterization service including complication rates, morbidity and mortality,
436 success rates and the number of procedures performed.
- 437 (D) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization
438 procedures shall perform, as the primary operator, a minimum of 75 adult therapeutic cardiac
439 catheterization procedures per year in the second 12 months after being credentialed to and annually
440 thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization
441 procedures performed by that physician in any combination of hospitals.
- 442 (E) Each physician credentialed by a hospital to perform pediatric diagnostic cardiac catheterizations
443 shall perform, as the primary operator, a minimum of 50 pediatric diagnostic cardiac catheterization
444 procedures per year in the second 12 months after being credentialed and annually thereafter. The
445 annual case load for a physician means pediatric diagnostic cardiac catheterization procedures
446 performed by that physician in any combination of hospitals
- 447 (F) Each physician credentialed by a hospital to perform pediatric therapeutic cardiac
448 catheterizations shall perform, as a primary operator, a minimum of 25 pediatric therapeutic cardiac
449 catheterizations per year in the second 12 months after being credentialed and annually thereafter. The
450 annual case load for a physician means pediatric therapeutic cardiac catheterization procedures
451 performed by that physician in any combination of hospitals
- 452 (G) An adult diagnostic cardiac catheterization service shall have a minimum of two appropriately
453 trained physicians on its active hospital staff. The Department MAY ACCEPT OTHER evidence OR
454 SHALL CONSIDER IT appropriate training if the staff physicians:
- 455 (I) are trained consistent with the recommendations of the American College of Cardiology;
456 (II) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and
457 (III) have each performed a minimum of 100 adult diagnostic cardiac catheterizations in the preceding
458 12 months.
- 459 (H) An adult therapeutic cardiac catheterization service shall have a minimum of two appropriately
460 trained physicians on its active hospital staff. The Department MAY ACCEPT OTHER evidence OR
461 SHALL CONSIDER IT appropriate training if the staff physicians:
- 462 (I) are trained consistent with the recommendations of the American College of Cardiology;
463 (II) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and
464 (III) have each performed a minimum of 75 adult therapeutic cardiac catheterization procedures in the
465 preceding 12 months.
- 466 (I) A pediatric cardiac catheterization service shall HAVE AN appropriately trained physician on ITS
467 active hospital staff. The Department MAY ACCEPT OTHER evidence OR SHALL CONSIDER IT
468 appropriate training if the staff physician:
- 469 (I) IS board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;
470 (II) IS credentialed by the hospital to perform pediatric cardiac catheterizations; and
471 (III) HAS trained consistently with the recommendations of the American College of Cardiology.

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

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

480
 481 (3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

482 (A) The SERVICE shall accept referrals for cardiac catheterization from all appropriately licensed
 483 practitioners.

484 (B) THE SERVICE shall participate in Medicaid at least 12 consecutive months within the first two
 485 years of operation and annually thereafter.

486 (C) THE SERVICE SHALL not deny cardiac catheterization services to any individual based on ability
 487 to pay or source of payment.

488 (D) THE OPERATION OF AND REFERRAL OF PATIENTS TO THE CARDIAC CATHETERIZATION
 489 SERVICE SHALL BE IN CONFORMANCE WITH 1978 PA 368, SEC. 16221, AS AMENDED BY 1986 PA
 490 319; MCL 333.1621; MSA 14.15 (16221).

491
 492 (4) Compliance with THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

493 (A) THE SERVICE SHALL BE OPERATING AT OR ABOVE THE APPLICABLE VOLUMES IN THE
 494 SECOND 12 MONTHS OF OPERATION OF THE SERVICE, OR AN ADDITIONAL LABORATORY, AND
 495 ANNUALLY THEREAFTER:

496 (I) 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT DIAGNOSTIC CARDIAC
 497 CATHETERIZATION PROCEDURES.

498 (II) 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT THERAPEUTIC CARDIAC
 499 CATHETERIZATION PROCEDURES.

500 (III) 600 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PEDIATRIC CARDIAC
 501 CATHETERIZATION PROCEDURES.

502 (IV) 500 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A RURAL OR MICROPOLITAN
 503 COUNTY WITH ONE LABORATORY.

504 (V) 750 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A METROPOLITAN COUNTY WITH
 505 ONE LABORATORY.

506 (VI) 1,000 PROCEDURE EQUIVALENTS PER CARDIAC CATHETERIZATION LABORATORY FOR
 507 TWO OR MORE LABORATORIES.

508 (VII) 36 ADULT PRIMARY PCI CASES FOR A PRIMARY PCI SERVICE.

509 (VIII) 350 ADULT PCI CASES FOR AN ELECTIVE PCI SERVICE WITHIN ONE-HOUR DRIVE TIME
 510 OF AN EXISTING HOSPITAL WITH AN OPEN HEART SURGICAL SERVICE.

511 (IX) 250 ADULT PCI CASES FOR AN ELECTIVE PCI SERVICE MORE THAN ONE-HOUR DRIVE
 512 TIME OF AN EXISTING HOSPITAL WITH AN OPEN HEART SURGICAL SERVICE.

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

517 (C) The HOSPITAL shall participate in a quality improvement data registry administered by the
 518 Department or its designee. The HOSPITAL SHALL submit summary reports as required by the
 519 Department. The HOSPITAL shall provide the required data in a format established by the Department or
 520 its designee. The HOSPITAL IS liable for the cost of data submission and on-site reviews in order for the
 521 Department to verify and monitor volumes and assure quality. THE HOSPITAL MUST become a member
 522 of the data registry upon initiation of the service and continue to participate annually thereafter FOR THE
 523 LIFE OF THAT SERVICE.

524

- 525 (5) COMPLIANCE WITH THE FOLLOWING PRIMARY PCI REQUIREMENTS, IF APPLICABLE:
526 (A) THE requirements set forth in Section 3(4).
527 (B) THE HOSPITAL shall immediately report to the Department any changes in the interventional
528 cardiologists who perform the primary PCI procedures.
529 (C) The HOSPITAL shall perform a minimum of 36 primary PCI procedures at the HOSPITAL in the
530 preceding 12-month PERIOD OF OPERATION OF THE SERVICE and annually thereafter.
531 (D) THE HOSPITAL SHALL MAINTAIN A 90-MINUTE DOOR-TO-BALLON TIME OR LESS IN AT
532 LEAST 75% OF THE PRIMARY PCI SESSIONS.
533 (E) The HOSPITAL shall participate in a data registry, administered by the Department or its
534 designee. The Department or its designee shall require that the applicant submit data on all consecutive
535 cases of primary PCI as is necessary to comprehensively assess and provide comparative analyses of
536 case selection, processes and outcome of care, and trend in efficiency. The applicant shall provide the
537 required data in a format established by the Department or its designee. The applicant shall be liable for
538 the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes
539 and assure quality.
540
- 541 (6) COMPLIANCE WITH THE FOLLOWING ELECTIVE PCI REQUIREMENTS, IF APPLICABLE:
542 (A) THE REQUIREMENTS SET FORTH IN SECTION 3(5).
543 (B) THE HOSPITAL SHALL PARTICIPATE IN A BENCHMARKED PCI DATA REGISTRY
544 DESIGNED BY THE DEPARTMENT THAT INCLUDES ALL THE FOLLOWING:
545 (I) PATIENT AND CLINICAL DESCRIPTIONS.
546 (II) MEASURES OF OUTCOMES.
547 (III) MEASURE OF THE ACC APPROPRIATE USE OF THE PROCEDURE INCLUDING STS OR
548 SYNTAX SCORE IN EACH PATIENT. THE DEPARTMENT SHALL REQUIRE THAT THE HOSPITAL
549 SUBMIT DATA ON ALL PCI CASES IN A FORMAT ESTABLISHED BY THE DEPARTMENT. THE
550 HOSPITAL SHALL BE LIABLE FOR COSTS OF DATA SUBMISSION. THE DEPARTMENT SHALL
551 REQUIRE THAT THE HOSPITAL SUBMIT A SUMMARY REPORT ON AN ANNUAL BASIS THAT
552 SHALL BE MADE AVAILABLE TO THE GENERAL PUBLIC.
553 (C) THE HOSPITAL SHALL PARTICIPATE IN AN EXTERNAL IMPARTIAL OVERSIGHT BODY TO
554 BE DESIGNATED BY THE DEPARTMENT. THE HOSPITAL SHALL BE LIABLE FOR THE COSTS OF
555 PARTICIPATING IN THIS OVERSIGHT PROCESS AND MUST CONTINUE TO PARTICIPATE
556 ANNUALLY THEREAFTER. THE OVERSIGHT BODY SHALL PRODUCE AN ANNUAL REPORT OF
557 ALL PCI PROGRAM THAT WILL CONTAIN ALL THE FOLLOWING:
558 (I) COMPLICATION RATES.
559 (II) NUMBER OF PROCEDURES PERFORMED PER OPERATOR.
560 (III) SUCCESS RATES.
561 (IV) APPROPRIATE USE RATES.
562 (V) PATIENT TRANSFER RATES.
563 (VI) THE OVERSIGHT BODY SHALL REVIEW THE FINDINGS WITH EACH OF THE
564 PARTICIPATING HOSPITALS AS A GROUP AND SHALL PROVIDE THOSE FINDINGS TO THE
565 DEPARTMENT TO BE MADE AVAILABLE TO THE GENERAL PUBLIC. ALL ELECTIVE PCI
566 SERVICES PERFORMING LESS THAN 250 PCI CASES PER YEAR IN ANY GIVEN YEAR MUST
567 HAVE ALL CASES REVIEWED BY THIS OVERSIGHT BODY FOR APPROPRIATENESS AND
568 OUTCOMES.
569 (D) THE HOSPITAL SHALL INCLUDE IN THEIR CONSENT FOR PCI NOTIFICATION TO THE
570 PATIENT THAT THE HOSPITAL DOES NOT PROVIDE ON-SITE OPEN HEART SURGICAL SERVICES
571 AND THAT TRANSFER TO A HOSPITAL WITH OPEN HEART SURGICAL SERVICES MAY BE
572 NECESSARY.
573 (E) THE HOSPITAL SHALL ESTABLISH AN INTERNAL REVIEW BODY, INCLUDING AT A
574 MINIMUM THE CHIEF MEDICAL OFFICER, DIRECTOR OF CARDIOVASCULAR SERVICES,
575 DIRECTOR OF CARDIOVASCULAR SERVICES FOR THE HOSPITAL WITH OPEN HEART SURGICAL
576 SERVICES (OR EQUIVALENT PHYSICIAN REPRESENTATIVES), THAT SHALL REVIEW AT LEAST
577 ANNUAL REPORTS DESCRIBING THE ACTIVITIES OF THE CARDIAC CATHETERIZATION SERVICE

578 INCLUDING COMPLICATION RATES, MORBIDITY AND MORTALITY, SUCCESS RATES AND THE
579 NUMBER OF PROCEDURES PERFORMED AND PROCEDURES REQUIRING TRANSFER.

580 (F) THE HOSPITAL SHALL EMPLOY APPROPRIATE DATA MANAGEMENT PERSONNEL TO
581 INSURE TIMELY AND ACCURATE REPORTING TO THE REGISTRY AND REVIEWING BODIES
582 STATED ABOVE.

583 (G) EACH PHYSICIAN CREDENTIALLED BY A HOSPITAL TO PERFORM PCI CASES SHALL
584 PERFORM, AS THE PRIMARY OPERATOR, A MINIMUM OF 100 PCI CASES PER YEAR IN THE
585 SECOND 12 MONTHS AFTER BEING CREDENTIALLED AND ANNUALLY THEREAFTER. THE
586 ANNUAL CASE LOAD FOR A PHYSICIAN MEANS PCI CASES PERFORMED BY THAT PHYSICIAN IN
587 ANY COMBINATION OF HOSPITALS.

588 (H) EACH PHYSICIAN MUST ALSO MAINTAIN THE FOLLOWING IN ORDER TO BE
589 CREDENTIALLED:

590 (I) PARTICIPATION IN AN INSTITUTIONAL QUALITY IMPROVEMENT PROGRAM.

591 (II) BOARD CERTIFIED IN INTERVENTIONAL CARDIOLOGY.

592 (III) PERFORMED AT LEAST 300 PCI CASES TOTAL SINCE FELLOWSHIP.

593 (IV) AT LEAST 30 HOURS OF CONTINUING MEDICAL EDUCATION DIRECTED TOWARD
594 INTERVENTIONAL CARDIOLOGY EVERY 24 MONTHS.

595 (I) THE MEDICAL DIRECTOR OF THE HOSPITAL SHALL PERFORM PCI PROCEDURES AT
596 THE CONTRACTED HOSPITAL WITH OPEN HEART SURGICAL SERVICES AND SHALL ALSO
597 PERFORM PCI PROCEDURES AT THE ELECTIVE PCI SERVICE HOSPITAL DURING EACH YEAR
598 UNTIL THE HOSPITAL REACHES MINIMUM VOLUME.

599 (J) THE HOSPITAL SHALL ALWAYS HAVE IN PLACE A WRITTEN AGREEMENT MEETING ALL
600 OF THE REQUIREMENTS OF THE WRITTEN AGREEMENT BETWEEN THE HOSPITAL AND THE
601 HOSPITAL WITH THE OPEN HEART SURGICAL SERVICE AS LONG AS THE ELECTIVE PCI
602 SERVICE DOES NOT HAVE ON-SITE OPEN HEART SURGICAL SERVICES, BUT MAY CHANGE THE
603 CONTRACTED OPEN HEART SURGICAL HOSPITAL.

604

605 **Section 9. Methodology for computing cardiac catheterization equivalents**

606

607 Sec. 9. The following shall be used in calculating PROCEDURE EQUIVALENTS and evaluating
608 utilization of a cardiac catheterization SERVICE AND ITS laboratories:

609

PROCEDURE TYPE	PROCEDURE EQUIVALENT	
	Adult	Pediatric
Diagnostic cardiac catheterization/PERIPHERAL SESSIONS	1.5	2.7
Therapeutic cardiac catheterization/PERIPHERAL SESSIONS	2.7	4.0
COMPLEX PERCUTANEOUS VALVULAR SESSIONS*	4.0	7.0
* COMPLEX PERCUTANEOUS VALVULAR SESSIONS INCLUDES, BUT IS NOT LIMITED TO, PROCEDURES PERFORMED PERCUTANEOUSLY OR WITH SURGICAL ASSISTANCE TO REPAIR OR REPLACE AORTIC, MITRAL AND PULMONARY VALVES SUCH AS TRANSCATHETER AORTIC VALVULAR IMPLANTATION (TAVI) PROCEDURES. THESE SESSIONS CAN ONLY BE PERFORMED AT HOSPITALS APPROVED WITH OPEN HEART SURGERY SERVICES.		

610

611 **Section 10. Documentation of projections**

612

613 Sec. 10. An applicant required to project volumes shall DEMONSTRATE THE FOLLOWING, AS
614 APPLICABLE TO THE PROPOSED PROJECT:

615

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

619

620 (2) AN APPLICANT PROPOSING TO INITIATE A PRIMARY PCI SERVICE SHALL
 621 DEMONSTRATE AND CERTIFY THAT THE HOSPITAL TREATED OR TRANSFERRED 36 ST
 622 SEGMENT ELEVATION AMI CASES DURING THE MOST RECENT 12-MONTH PERIOD PRECEDING
 623 THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT. CASES MAY INCLUDE
 624 THROMBOLYTIC ELIGIBLE PATIENTS DOCUMENTED THROUGH PHARMACY RECORDS
 625 SHOWING THE NUMBER OF DOSES OF THROMBOLYTIC THERAPY ORDERED AND MEDICAL
 626 RECORDS OF EMERGENCY TRANSFERS OF AMI PATIENTS TO AN APPROPRIATE HOSPITAL
 627 FOR A PRIMARY PCI PROCEDURE.

628

629 (3) AN APPLICANT PROPOSING TO INITIATE AN ELECTIVE PCI SERVICE SHALL
 630 DEMONSTRATE AND CERTIFY THE FOLLOWING:

631 (A) PHYSICIAN COMMITMENTS OF PCI CASES PERFORMED AT AN EXISTING CARDIAC
 632 CATHETERIZATION SERVICE IN THE SAME HEALTH SERVICE AREA.

633 (I) COMMITMENTS OF PCI CASES SHALL NOT REDUCE AN EXISTING CARDIAC
 634 CATHETERIZATION SERVICE BELOW ITS APPLICABLE VOLUME REQUIREMENT.

635 (II) COMMITMENTS OF PCI CASES DO NOT REPRESENT DUPLICATE CASES WITHIN THIS
 636 SUBSECTION.

637 (III) COMMITMENTS IDENTIFY THE FOLLOWING:

638 (A) THE NAME OF EACH PHYSICIAN THAT PERFORMED PCI CASES TO BE COMMITTED TO
 639 THE PROPOSED PROJECT.

640 (B) THE NUMBER OF PCI CASES THAT EACH PHYSICIAN PERFORMED DURING THE MOST
 641 RECENT 12 MONTHS VERIFIABLE BY THE DEPARTMENT.

642 (C) THE LOCATIONS AT WHICH THE COMMITTED PCI CASES WERE PERFORMED.

643 (D) A WRITTEN COMMITMENT FROM EACH PHYSICIAN THAT HE OR SHE WILL PERFORM AT
 644 LEAST THE VOLUME OF PCI CASES COMMITTED TO THE PROPOSED ELECTIVE PCI SERVICE
 645 FOR NO LESS THAN THREE YEARS SUBSEQUENT TO THE INITIATION OF THE SERVICE
 646 PROPOSED BY THE APPLICANT.

647 (E) THE NUMBER OF PCI CASES PERFORMED AT THE EXISTING CARDIAC
 648 CATHETERIZATION SERVICE FROM WHICH PCI CASES WILL BE TRANSFERRED DURING THE
 649 MOST RECENT 12- MONTH PERIOD VERIFIABLE BY THE DEPARTMENT FOR WHICH ANNUAL
 650 SURVEY DATA IS AVAILABLE.

651 (B) DOCUMENTATION OF EXISTING PATIENT TRANSFERS FROM THE APPLICANT HOSPITAL
 652 TO A PCI SERVICE OR OPEN HEART SURGERY HOSPITAL FOR PURPOSES OF RECEIVING A PCI
 653 PROCEDURE. IN DEMONSTRATING COMPLIANCE, AN APPLICANT SHALL PROVIDE THE
 654 FOLLOWING FOR EACH PATIENT TRANSFER IN THE MOST RECENT 12-MONTH PERIOD
 655 VERIFIABLE BY THE DEPARTMENT:

656 (I) UNIQUE PATIENT IDENTIFIER.

657 (II) ICD-9, OR EQUIVALENT, DIAGNOSIS CODE.

658 (III) HOSPITAL WHERE THE PATIENT WAS TRANSFERRED.

659 (IV) PHYSICIAN PATIENT TRANSFERRED TO.

660 (V) DATE OF PATIENT TRANSFER.

661 (C) EXISTING PCI CASES PERFORMED AT THE APPLICANT HOSPITAL IN THE MOST RECENT
 662 12 MONTHS VERIFIABLE BY THE DEPARTMENT.

663

664 **Section 11. Comparative reviews; Effect on prior CON Review Standards**

665

666 Sec. 11. PROPOSED projects reviewed under these standards shall not be subject to comparative
 667 review. These CON Review Standards supercede and replace the CON Review Standards for Cardiac
 668 Catheterization Services approved by the CON Commission on DECEMBER 11, 2007 and effective on
 669 FEBRUARY 25, 2008.

APPENDIX A

670				
671				
672	HEALTH SERVICE AREAS	COUNTIES		
673				
674	1 – SOUTHEAST	LIVINGSTON	MONROE	ST. CLAIR
675		MACOMB	OAKLAND	WASHTENAW
676		WAYNE		
677				
678	2 – MID-SOUTHERN	CLINTON	HILLSDALE	JACKSON
679		EATON	INGHAM	LENAWEE
680				
681	3 – SOUTHWEST	BARRY	CALHOUN	ST. JOSEPH
682		BERRIEN	CASS	VAN BUREN
683		BRANCH	KALAMAZOO	
684				
685	4 – WEST	ALLEGAN	MASON	NEWAYGO
686		IONIA	MECOSTA	OCEANA
687		KENT	MONTCALM	OSCEOLA
688		LAKE	MUSKEGON	OTTAWA
689				
690	5 - GLS	GENESEE	LAPEER	SHIAWASSEE
691				
692	6 – EAST	ARENAC	HURON	ROSCOMMON
693		BAY	IOSCO	SAGINAW
694		CLARE	ISABELLA	SANILAC
695		GLADWIN	MIDLAND	TUSCOLA
696		GRATIOT	OGEMAW	
697				
698	7 – NORTHERN LOWER	ALCONA	CRAWFORD	MISSAUKEE
699		ALPENA	EMMET	MONTMORENCY
700		ANTRIM	GRAND TRAVERSE	OSCODA
701		BENZIE	KALKASKA	OTSEGO
702		CHARLEVOIX	LEELANAU	PRESQUE ISLE
703		CHEBOYGAN	MANISTEE	WEXFORD
704				
705	8 – UPPER PENINSULA	ALGER	GOGEBIC	MACKINAC
706		BARAGA	HOUGHTON	MARQUETTE
707		CHIPPEWA	IRON	MENOMINEE
708		DELTA	KEWEENAW	ONTONAGON
709		DICKINSON	LUCE	SCHOOLCRAFT

APPENDIX B

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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