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

Wednesday April 20, 2011

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

APPROVED MINUTES

I. Call to Order

Vice-Chairperson Palmer called the meeting to order @ 9:37 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
Robert Goodman, MD, MHSA, FACEP, Blue Cross Blue Shield/Blue arrived@ 9:46 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 via conference call @ 9:48 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. Members Absent:

Kim Eagle, MD, Chairperson, University of Michigan Health System

C. 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 March 10, 2011

Motion by Mr. Buxton and seconded by Dr. Weaver to accept the minutes as presented. Motion carried in a vote of 16- Yes, 0- No, and 0- Abstain.

IV. Review of Agenda

Motion by Mr. Buxton and seconded by Dr. Lewis to accept the agenda as modified consolidating Items 5 and 8 for presentation together. Motion carried.

V. Presentation and Further Discussion of Equivalents and Primary PCI

Dr. Pielsticker gave a brief overview of the Standards and proposed changes as it relates to primary PCI (See attachment A).

Discussion followed.

Dr. Lewis gave provided a brief overview of Part II (See attachment A) on equivalents.

Discussion followed.

Break @ 10:43 a.m. - 11:00 a.m.

VI. Presentation and Further Discussion regarding Detailed Cost and Financial Analysis

Dr. Riba gave a brief overview of potential costs for elective PCI without on-site surgery (See attachment B).

Dr. Goodman provided brief comments on discussion points.

Mr. Buxton gave a brief overview of Cost to Reimbursement Comparison Analysis (See attachment C).

Discussion followed.

VII. Potential Draft Language for elective PCI Without On-Site Surgical Back-Up

Dr. Weaver gave a brief overview of the draft language presented (See attachments D & E).

Discussion followed.

VIII. Public Comment

Robert Meeker, Spectrum Health
Dr. Mike Jaggi, Hurley Medical Center
Susan Heck, Hurley Medical Center
Ken Nysson, Metro Health

IX. Review of Charges (See attachment F)

Motion by Dr. Weaver and seconded by Dr. Dobies to accept Charge 1 with continued regulation of cardiac catheterization services. Motion Carried in a vote of 17-Yes, 0- No, and 0- Abstain.

Motion by Dr. Schreiber and seconded by Mr. Buxton to accept charge 2 allowing elective PCI without surgical back-up incorporating the draft language presented (See attachment E) with amended provisions to 5(1)(c)(vii). The Department may modify as necessary. Motion Carried in a vote of 9- Yes, 8- No, and 0- Abstain.

Motion by Dr. Lewis and seconded by Dr. Schreiber to accept charge 3 incorporating the proposal presented by Dr. Lewis (See attachment A). Motion Carried in a vote of 17-Yes, 0-No, and 0- Abstain.

Motion by Dr. Lewis and seconded by Dr. Weaver to accept charge 4 including the adult and pediatric recommendations and modifications to the volume requirements: 1,000 to maintain and 1,400 to expand. Motion Carried in a vote of 17- Yes, 0-No, and 0- Abstain.

Motion by Dr. Pielsticker and seconded by Dr. Lewis to accept charge 5 incorporating the proposal presented by Dr. Pielsticker (See attachment A) including 400 of the 500 procedure equivalents must be coronary cardiac catheterization procedures. Motion Carried in a vote of 14- Yes, 2- No, and 1- Abstain.

Motion by Dr. Weaver and seconded by Dr. Sottile to not allow initiation of new diagnostic cardiac catheterization labs if the Commission accepts the recommendation to allow elective PCI without surgical back-up. Motion Carried in a vote of 14- Yes, 1- No, and Abstain- 3.

Motion by Dr. Weaver and seconded by Dr. Sottile to allow placement of pacemakers/ICD implantations within a multi-purpose room, without CON approval for existing cardiac catheterization services. Motion defeated in a vote of 3- Yes, 8-No, and 6- Abstain.

X. Next Steps and Future Agenda Items

Dr(s). Riba and Dobies will present their findings to the SAC related to pacemakers/ICD implantations within multi-purpose rooms.

The Department will review the draft language to ensure consistency throughout the Standards.

XI. Future Meeting Dates

A. May 4, 2011

XII. Adjournment

Motion by Mr. Buxton and seconded to adjourn the meeting @ 1:18 p.m. Motion Carried.

Certificate of Need
Current Cardiac Catheterization Standards and Proposed Changes

Liz Pielsticker, MD
Barry Lewis, DO
Bart Buxton, Ed.D

April 20, 2011

OVERVIEW

Dr. Liz Pielsticker – Part I

- Recommendations from March 10, 2011
- Requirements for Replacement of Equipment
- Requirements for Primary PCI

Dr. Barry Lewis – Part II (Volumes & Weights)

Summary of Recommendations from March 10, 2011

Recommended:

- No changes to program and volume requirements to initiate cardiac catheterization services.
- Continuing volume requirements for replacement of equipment, including a slight increase in the volume requirement for pediatric laboratories.
- Continuing volume requirements for adding laboratories to existing cardiac catheterization services.
- Elimination mobile cardiac catheterization network language.
- Allowing peripheral procedures to be counted for initiation, replacement, and expansion of services.

3

Requirements for Replacement of Laboratory Equipment

Previous Recommendation:

- Continue volume requirements for replacement of equipment, including a slight increase in the volume requirement for pediatric laboratories.

Proposed Change:

- Sec. 8. 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 other equipment or software used in the laboratory. An applicant proposing to replace a cardiac catheterization laboratory shall demonstrate the following as applicable to the proposed project.

4

Requirements for Replacement of Laboratory Equipment continued…

- Sec. (8) (1) An applicant proposing to replace a cardiac catheterization laboratory or laboratories at the same hospital site shall demonstrate the following:
- (a) The angiography X-ray equipment to be replaced is fully depreciated according to generally accepted accounting principles or either meets either of the following:
- (i) The existing angiography X-ray equipment 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.

5

Requirements for Replacement of Laboratory Equipment continued…

- (b) The existing angiography X-ray equipment will removed from service on or before beginning operations of the replacement equipment.
- *Summary*: No volume requirement to replace laboratory equipment and no CON review/approval needed to upgrade equipment. The Department will address language for replacing a service to a new site.

6

Requirements for Primary PCI

Current Primary PCI Requirements:

- Sec. 2(1)(v) "Primary percutaneous coronary intervention (PCI)" means a PCI performed within 120 minutes for emergency acute myocardial infarction (AMI) patients seen in the emergency room (ER) with confirmed ST elevation or new left bundle branch block.

Proposed Change:

- (v) "Primary percutaneous coronary intervention (PCI)" means a PCI performed on acute myocardial infarction (AMI) patients with confirmed ST elevation or new left bundle branch block.
- *Summary*: Move/change door-to-balloon requirement to Project Delivery Requirements and eliminate where the patient presented.

Requirements for Primary PCI continued…

Current Primary PCI Requirements:

- Sec. 5(1)(a) The applicant's adult diagnostic cardiac catheterization service performed a minimum of 400 diagnostic procedures (excluding diagnostic electrophysiology studies and right heart catheterizations) during the most recent 12 months preceding the date the application was submitted to the Department. Mobile cardiac catheterization laboratories are not eligible to apply under Section 5.

Proposed Change:

- (a) The existing cardiac catheterization service performed a minimum of 500 procedures equivalents during the most recent 12 months preceding the date the application was submitted to the Department.
- *Summary*: Change still assures competency of laboratory service.

Requirements for Primary PCI continued…

Current Primary PCI Requirements:

- Section 5(1)(b) The interventional cardiologists (at least two) to perform the primary PCI are experienced interventionalists who have each performed at least 75 interventions annually as the primary operator at an open heart surgery facility during the most recent 24 months preceding the date the application was submitted to the Department, and annually thereafter.

Proposed Change:

- None. Continued support for this requirement.

Requirements for Primary PCI continued…

Current Primary PCI Requirements:

- Sec. 5(2) An applicant shall project a minimum of 48 primary PCI procedures will be performed in the second 12 months of operation after initiation of service, and annually thereafter. Primary PCI volume shall be projected by documenting, as outlined in Section 13, and certifying that the applicant treated or transferred enough ST segment elevation AMI cases during the most recent 12 months preceding the date the application was submitted to the Department to maintain 48 primary PCI cases annually. Factors that may be considered in projecting primary PCI volume are the number of thrombolytic eligible patients per year seen in the Emergency Department (as documented through hospital pharmacy records showing the number of doses of thrombolytic therapy ordered for AMI in the Emergency Department) and/or documentation of emergency transfers to an open heart surgery facility for primary PCI.

Requirements for Primary PCI continued…

Proposed Change:

- Sec. 5(2) An applicant shall project a minimum of 36 primary PCI procedures will be performed in the second 12 months of operation after initiation of service, and annually thereafter. Primary PCI volume shall be projected in accordance with Section 14, and certified by the applicant that the hospital treated or transferred at least 36 ST segment elevation AMI cases during the most recent 12 months preceding the date the application was submitted to the Department. Factors that may be considered in projecting primary PCI volume are the number of thrombolytic eligible patients (as documented through hospital pharmacy records showing the number of doses of thrombolytic therapy ordered for AMI) and/or documentation of emergency transfers to an open heart surgery facility for primary PCI.
- *Summary*: Reduced projection to 36 eligible cases and eliminated where the patient was seen within the hospital.

Requirements for Primary PCI continued…

Current Primary PCI Requirements:

- Sec. 13(2) The applicant shall have performed a minimum of 36 primary PCI procedures at the facility in the preceding 12 months and annually thereafter.

Proposed Change:

- Sec. 13(2) The applicant shall have performed a minimum of 36 primary PCI procedures at the hospital in the second 12 months of operation after initiation of services, and annually thereafter. The primary PCI procedures performed are within 90 minutes from presentation of the patient.
- *Summary*: Modified requirement to 36 cases and 90 minute door-to-balloon time from 120 minutes.

In Summary

- Modify primary PCI requirements as previously described if this category of service remains.
- Modify volume requirements based on the methodology proposed by Dr. Lewis for initiation of diagnostic (if remains), primary PCI (if remains), therapeutic without onsite cardiac surgery (if approved), and therapeutic with onsite surgery.
- Retain all program requirements as is for initiation of diagnostic and therapeutic services pending SAC recommendation on types of services to be allowed in the future.

In Summary Continued…

- Eliminate volume requirements for replacement of equipment as recommended by the Department.
- Continue volume requirements for adding laboratories to existing services based on methodology proposed by Dr. Lewis.
- Allow peripheral procedures to be counted for initiation, replacement to new site and expansion.
- Eliminate mobile cardiac catheterization network language.

OVERVIEW

Dr. Barry Lewis – Part II

- Categories and Equivalents
  - Current
  - Proposed Adult
  - Proposed Pediatric
- Volume Requirements

15

Current Categories & Equivalents

PROCEDURE	ADULT EQUIVALENT	PEDIATRIC EQUIVALENT
DIAG CARDIAC CATH	1.0	3.0
THERAPEUTIC CARDIAC CATH	1.5	3.0
THERAPEUTIC OTHER	2.5	3.5
DIAG PERIPHERAL	1.0	2.0
THERAP PERIPH – SFA	2.5	2.5
THERAP - INFRAPOP	3.0	3.0
THERAP-AORTA	4.0	4.0
THERAP PERIP OTHERS	1.5	2.5
DIAGNOSTIC EP	2.0	3.5
PPM/ICD	2.5	5.0
ABLATION-NON AF/VT	3.0	5.0
ABLATION-AF OR VT	4.0	6.0
CARDIOVERSION	1.0	2.0
OTHER (IVC FILTER, IABP, ETC.)	1.0	2.0

Current Method

Requires patient count by session type along with count of procedures performed by various categories and weights. Total equivalency is reduced by .5 for each additional procedure done in a single session. Peripheral procedures are not counted when applying for an extra laboratory.

16

New Procedures

New Procedures Being Done in the Cath Lab Setting:

- Complex Ablations (left sided supraventricular/ventricular)
- Alcohol Septal Ablations
- Percutaneous ASD/PFO Closure
- Percutaneous Mitral Valve Repair
- Percutaneous Balloon Mitral Valvuloplasty
- Transcatheter Aortic Valve Implantation (TAVI)
- Percutaneous Balloon Aortic Valvuloplasty (part of TAVI)

17

New Procedures continued…

- Using same methods, overall average time for these procedures is approximately 4 hours. Thus, equivalent weight should be 4.

18

Adult Recommendation

Procedure equivalents:

- Diagnostics Only = 1.5
- Interventions = 2.7
- Percutaneous Valvular Procedures = 4.0

Pediatric Procedures

Procedures Reviewed at Two Facilities:

- Over 1100 Procedures
- Diagnostic Procedures (R/LHC) approximately 500 cases
- Average 2 – 2.5 hrs (75th percentile = 2 hr 12 min)
- Equivalent = 2.7

Interventions
"Lots of kinds, but few of each"

Procedures (not necessarily limited to these):

- Percutaneous Valve (Pulmonic) (20)
- 6 hr 19 min (75th percentile = 7 – 8 hr)
- ASD Occlusions (230)
- 3.25 hr (75th percentile = 4.5 hr)
- All Others (375)
- 2 hr 45 min (75th percentile = 3.5 hr)
- Valvuloplasty (aortic/pulmonic)
- SVC stents
- PDA occlusion
- Other angioplasties/occlusions

21

Other Factors to be Considered

- Newer guidelines insisting on Anesthesia present for all interventions
- Adds about 30 minutes to procedure
- All procedures may require general anesthesia
- Teaching facilities
- Experience of operators (senior operators quicker)

22

Pediatric Recommendation

Procedure equivalents:

- Diagnostic = 2.7
- Intervention = 4.0

Special thanks to:

Dr. Thomas Lloyd (UMHS)
Dr. Ronald Grifka (Spectrum Health)
Drs. Thomas Forbes & Albert Rocchini (Children's & UMHS)

Proposed Categories & Equivalents

PROCEDURE	ADULT EQUIVALENT	PEDIATRIC EQUIVALENT
DIAG ONLY	1.5	2.7
INTERVENTION	2.7	4.0
PERCUTANEOUS VALVULAR PROCEDURE	4.0	7.0

- Reduces complexity of methodology and makes it easier for providers to determine if they qualify for additional laboratories.
- Diagnostic only sessions include cardiac, peripheral and electrophysiology.
- Interventional sessions may include diagnostic followed by an intervention or intervention only for cardiac, peripheral and electrophysiology.
- Valvular sessions include any session where this type of procedure occurred.
- Patient counted in only one of the three categories, and shall be counted in the category of highest value based on the types of procedures performed.

Volume Requirement Recommendation

- 1,400 equivalents per lab to add an additional laboratory
- 1,000 equivalents per lab to maintain compliance

25

Volume Requirement Recommendation continued…

Table below shows the number of existing labs at 20 hospitals as well as the number of labs that could be added based on 2010 reported volumes as calculated under the current and proposed methodology.

Hospital - # of Existing Labs	Current Method	Proposed Method
Hospital A – 4	1	0
Hospital B – 6	1	2
Hospital C – 5	0	1
Hospital D – 1	(1)	0
Hospital E – 3	2	3
Hospital F – 6	2	0
Hospital G – 3	3	4
Hospital H – 1	0	0
Hospital I – 2	(1)	(1)
Hospital J – 3	0	3

Hospital - # of Existing Labs	Current Method	Proposed Method
Hospital K – 5	0	0
Hospital L – 9	7	1
Hospital M – 1	1	0
Hospital N – 1	1	0
Hospital O – 2	4	0
Hospital P – 2	(1)	0
Hospital Q – 6	0	4
Hospital R – 5	2	4
Hospital S – 7	1	3
Hospital T – 3	(1)	(1)

26

Questions & Answers

Thank You.

Cardiac Catheterization Standards Advisory Committee for the State of Michigan

Potential Costs of CC Lab Expansion and Relation to Access to Elective PCI

April 20, 2011

David Dobies, MD, FACC
Genesys Regional Medical Center
Sub-Committee Chair

Arthur L. Riba, MD, FACC
Oakwood Healthcare System
SAC Member

SAC & Committee Charge

- **Charge:**
  - Determine if elective therapeutic cardiac catheterizations (PCI) should be allowed at facilities that do not provide on-site open heart surgery services. If it is recommended that these services should be allowed, provide specific criteria for determining need for this service including patient safety and quality criteria.
- Policy Implications: Develop recommendations for CON Commission consideration based on assessment of the policy implications of current standards, and potential changes on the basis of *Quality, Cost, and Access.*
- Sub-Committee charged to evaluate the potential cost, quality and access of cardiac cath lab expansion to include PCI without surgical backup.

Lab Expansion Continuum

- Establish New Diagnostic Lab
- Diagnostic to Primary PCI
  - 18 Diagnostic Labs
  - Only 3 have 2 or more labs
- Primary PCI to Elective PCI
  - 11 Primary PCI Hospitals
  - Only 3 have 2 or more labs

Establishing New Lab

• Construction	$500,000
• X-Ray	$800,000
• Hemodynamic monitoring system	$140,000 – $200,000
• IVUS	$50,000 – $100,000
• Balloon Pump	$45,000
• Cardiology PACs System	$380,000
Subtotal:	**$1,965,000**

Capital Expansion 8 New labs - $1,965,000 x 8 = $15,720,000

Supplies

- Stents
- Catheters
- Balloons
- Wires

Total: Consignment

Staffing

- 350-400 pts a year with each pt requiring on average a 24-hr stay; including nurses – providing care for the pt, pre & post procedure, and Cath Lab techs
- 3 FTE @ $50,000 ea + 30% benefits = **$200,000**

Construction (additional)

- **Add'l pre/recovery areas** (depends upon existing facility configuration)
- **Add'l telemetry-monitored beds on the units** (depends upon existing facility configuration)

Diagnostic to Primary PCI

- Operating Cost (using variable cost approach)
  - Staff On Call (3 Nurses, 1 Tech 24/7)
    $200,000 + 30% Benefits
  - Quality Specialist/Database Coordinator
    $80,000 + 30% Benefits
  - On Call Physician **$0 - $3,000 per day**
  - Angiojet **$33,000**
  - IVUS **$50,000 - $100,000 vs. rental purchase agreement**
  - Supplies (catheters, wires, balloons, stents) **via consignment**
  - Balloon Pump **$45,000**

TOTAL COST ESTIMATE = $532,000

Primary to Elective PCI

- Quality Specialist $80,000 + 30% Benefits
- Database Manager $80,000 + 30% Benefits
- Supplies (catheters, wires, balloons, stents) – via consignment
- Additional staffing (RNs, techs) for increased case load
- IVUS $50,000 - $100,000 vs. imaging system with IVUS and FFR - $5,000/month x 6 months > purchase $120,000
- Second balloon pump $45,000

TOTAL COST ESTIMATE = $356,000

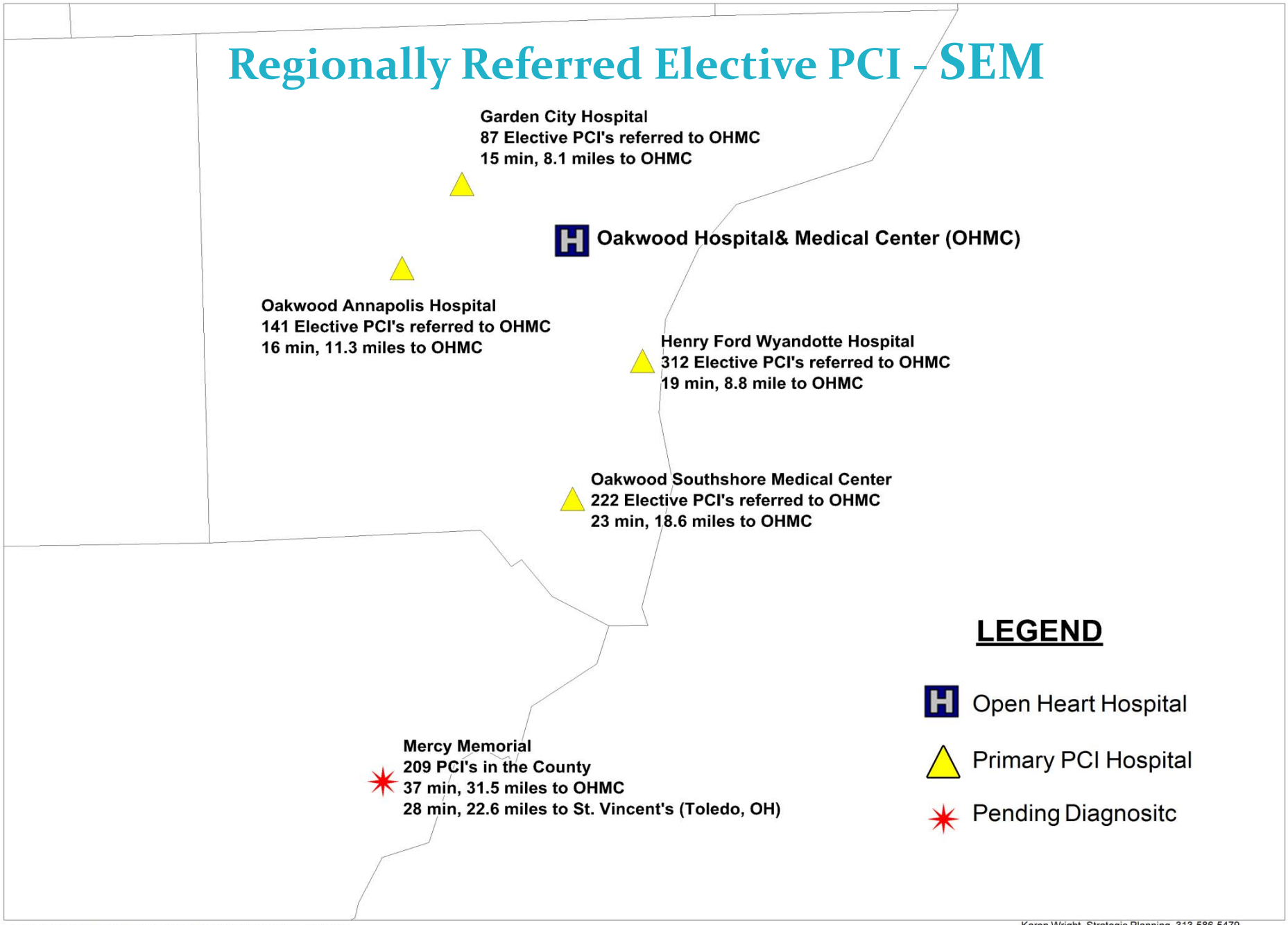
Split Procedures, Different Sites and on Same Day Summary

- BCBSM/BCN commercial and Medicare Advantage members only (about 4.5 million covered lives), paid claims data
  From 1/1/2008 to 7/31/2009 (18 month period)
  - Represents about 50% of the Michigan non-Medicare enrolled population
  - Represents about 18% of the Michigan Medicare enrollment (2009)

116 cases of PCI at different site than diagnostic cardiac catheterization, and on the same date, represent 0.26% of all BCBSM/BCN diagnostic cardiac catheterization events (45,235) during these 18 months among this universe of BCBSM/BCN members

- No cases were Medicare in this data

Regionally Referred Elective PCI - SEM



Note: Distances calculated using mapquest.com
Sources: MIDB (2009) and Internal OHMC data.

Karen Wright, Strategic Planning, 313-586-5479
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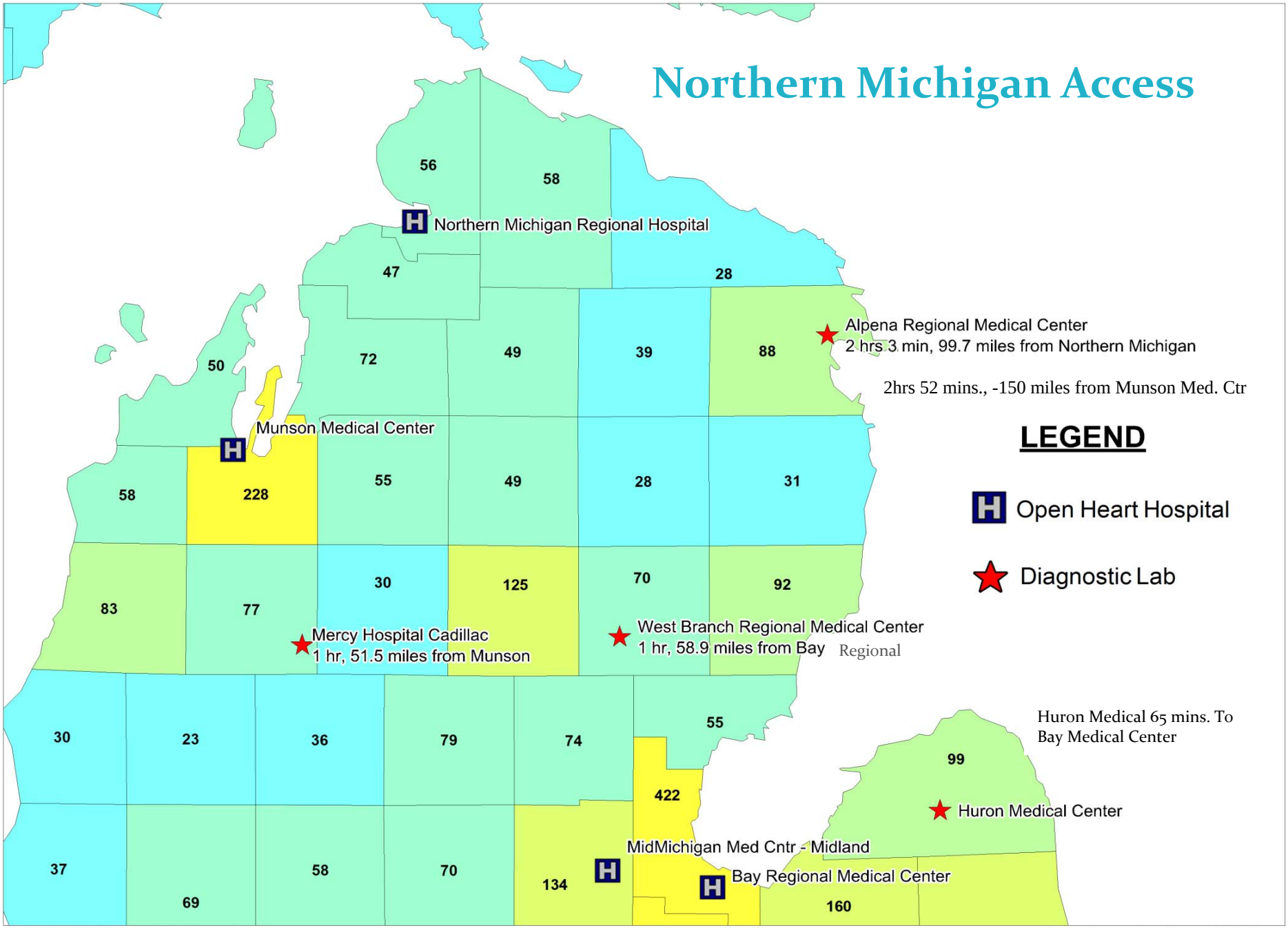

Note: Principal px = 37.21-37.23, 88.52-88.58
Source: MIDB (2009)

Strategic Planning, Karen Wright, 313-586-5479
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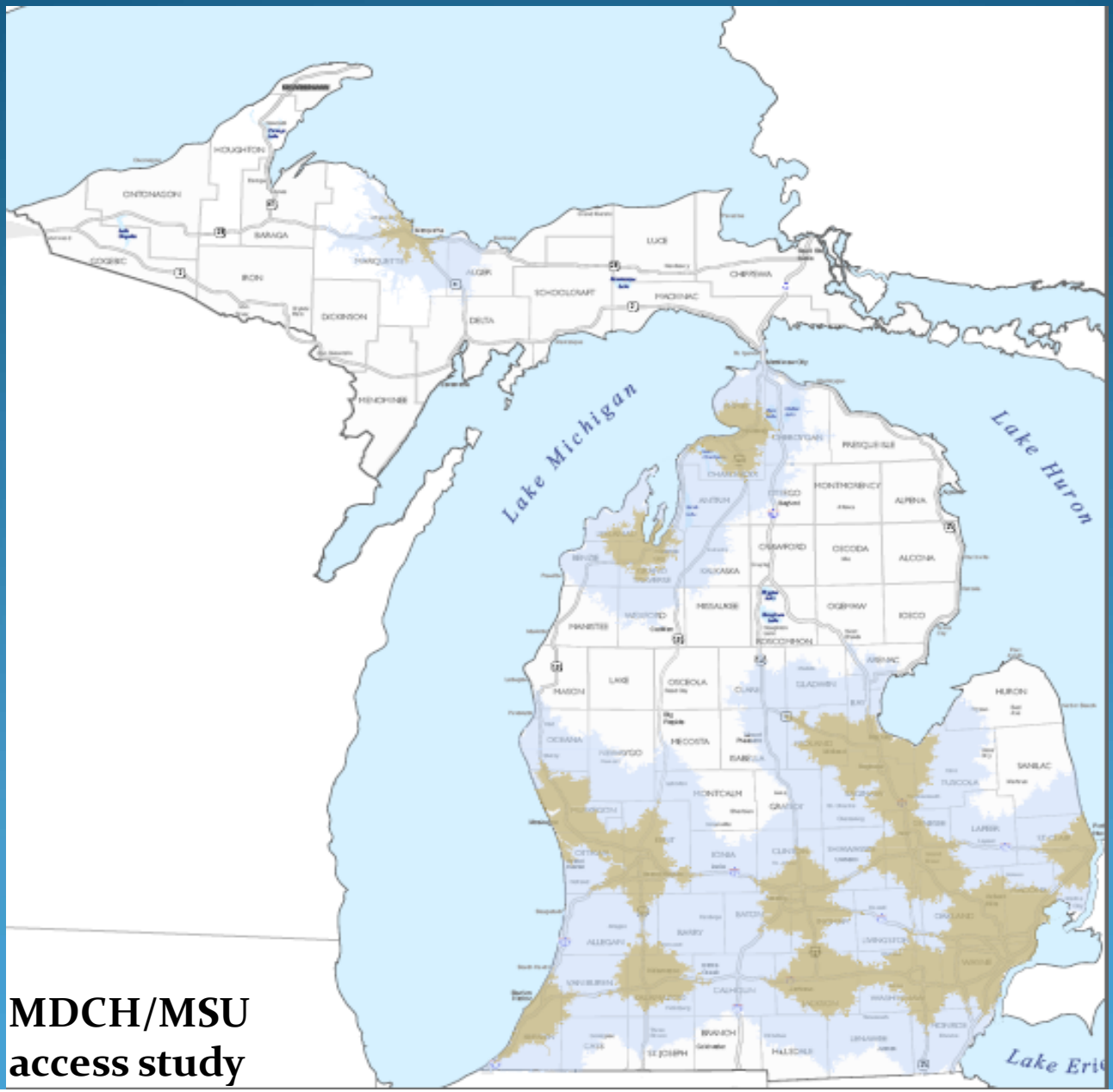
Elective PCI Access – 30 & 60 Minute Drive Time



MDCH/MSU access study

Access & Quality Implications of Increased Program Costs

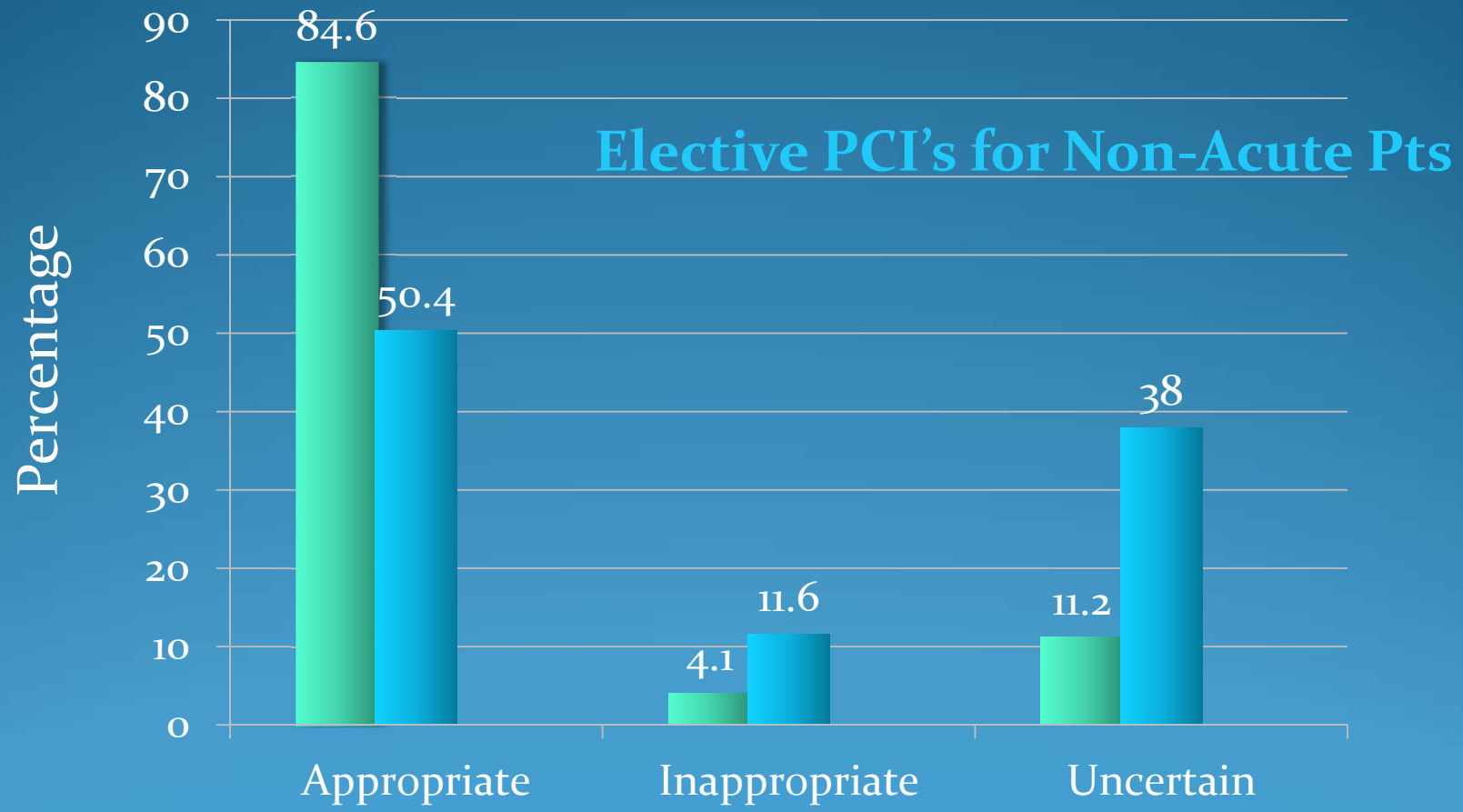
- There is no evidence that access to PCI is problematic in Michigan
- Michigan citizens have excellent access to PCI services.
  - 16 of the Top 20 zip codes based on volume are in Southeast Michigan, which are served by 17 hospitals.
  - Four other zips are Saginaw (3) and Benton Harbor (1) which offer local PCI/OHS programs.
  - None of the proponents for expansion are in underserved geographies

- MSU MDCH Geographic Access study indicated that 69% of Michigan citizens needing "Scheduled Only (No Emergency)" services live within 30 minute drive time of an existing OHS program and 91% live within 60 minute drive.
  - Access is not a problem for elective and ACS PCI patients in existing hospitals with diagnostic labs only and primary PCI-STEMI hospitals.

Appropriateness of PCI

Chan P, et al. ACC 2011 Scientific Session

- ACC-NCDR
- 7/09-6/10: > 500,000 cases (71% acute; 29% non-acute)



Conclusion:
Wide variation in rate of inappropriate PCI in non-acute situation < 10% to > 30%

PCI Unnecessary Utilization

Pennsylvania[1]

- Westmoreland Hospital, Pittsburgh had 141 patients that unnecessarily received stents

Maryland[2]

- Senate Finance Committee reports Maryland hospital implanted 585 unnecessary stents
- St. Joseph Center, Towson – Dr. Mark Midei implanted 369 unnecessary stents

California[3]

- Redding Medical Center – Two physicians had as many as 50% of their procedures were reported as unnecessary

1 *Patients may have gotten unneeded stents*, March 3, 2011
2 *Stent-happy docs on notice in Maryland health care fraud debate*, March 4, 2011
3 *The Redding affidavit: FBI report alleges unnecessary procedures while hospital stayed mum*, November 15, 2002

Michigan Society of Thoracic and Cardiovascular Surgeons and BMC2 Quality Collaborative March 5, 2011 Meeting

- Concept of "heart team" for ischemic heart disease patients in Michigan hospitals
  - "Heart Team" fosters communication between various CV specialists to create collaborative consensus/decision making to provide optimal care for patients
  - Assures Guideline recommended care based on clinical and anatomical risk
- Recently published European "Guidelines on Myocardial Revascularization" -- consultation should be obtained prior to PCI

"Approval of PCI without onsite Cardiac Surgery challenges these collaborative, thoughtful processes"

Source: Letter to Cardiac Cath SAC from Eric Hanson, M.D.; President, Michigan Society of Thoracic and Cardiovascular Surgeons; March 30, 2011

Conclusion

- *Costs* for new programs (capital and operating), regulatory compliance, regulatory oversight by MDCH, and potential supply side volume increases far outweigh occasional patient transfer costs.
- *Quality* will be challenged by potential unnecessary utilization to meet volume standards and consent bias
- From a public policy perspective considering the total healthcare costs to Michigan, current *Access* to services, and trend in declining need for revascularization - should we dramatically expand the number of labs by delinking elective PCI and OHS?

Standards Proposal

- Rural Hospital Standards
  - Improves access – closest Open Heart Hospital is more than 60 minute drive time
  - Volume of 300 or more Elective PCI cases
- Urban Hospital Standards
  - Improves access – closest Open Heart Hospital is more than 60 minute drive time
  - Volume of 400 or more Elective PCI cases

Catheterization Services

Cost to Reimbursement Comparison Analysis

Diagnostic and Therapeutic Populations

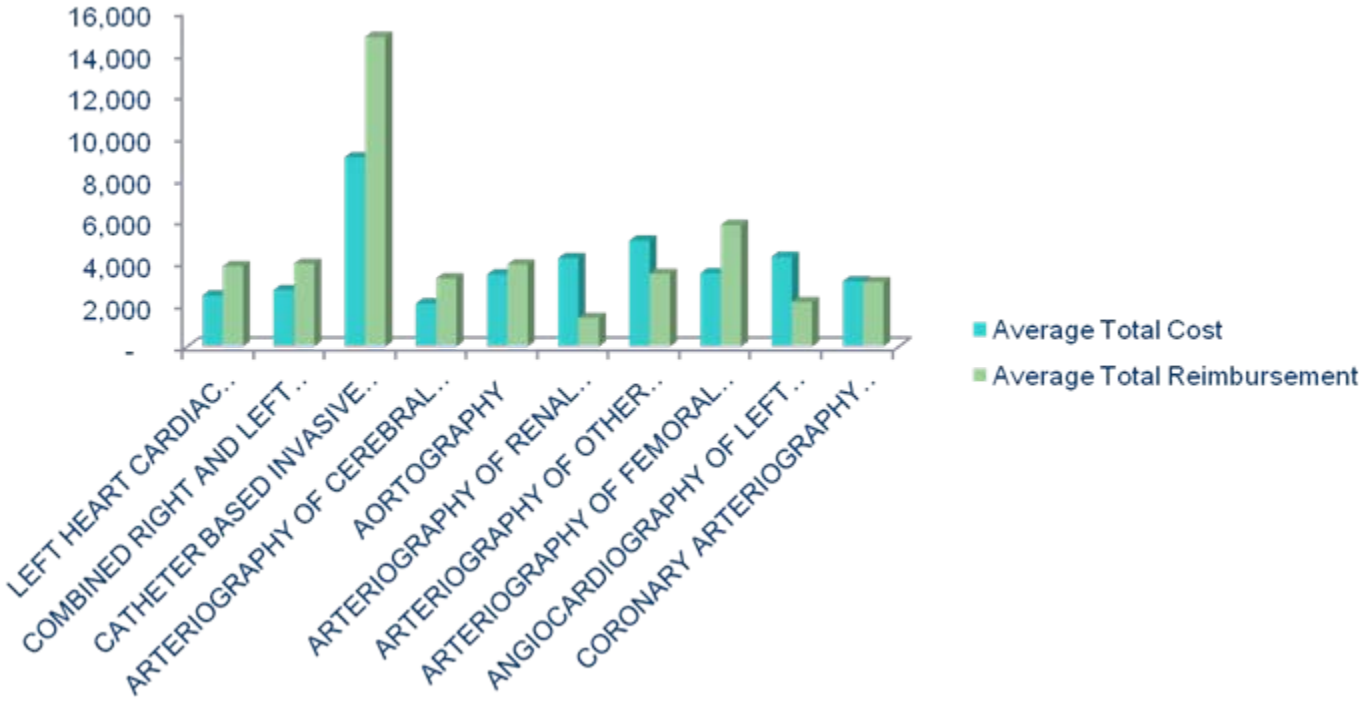
Submitted by:
Barton P. Buxton, EdD

Diagnostic Services Comparison

- Average Total Cost for Procedures are $4,757
- Average Total Reimbursement is $5,888
- Inpatient procedures account for 28% of population
- Outpatient population is 72% of population
- Margin average on diagnostic population is <12%

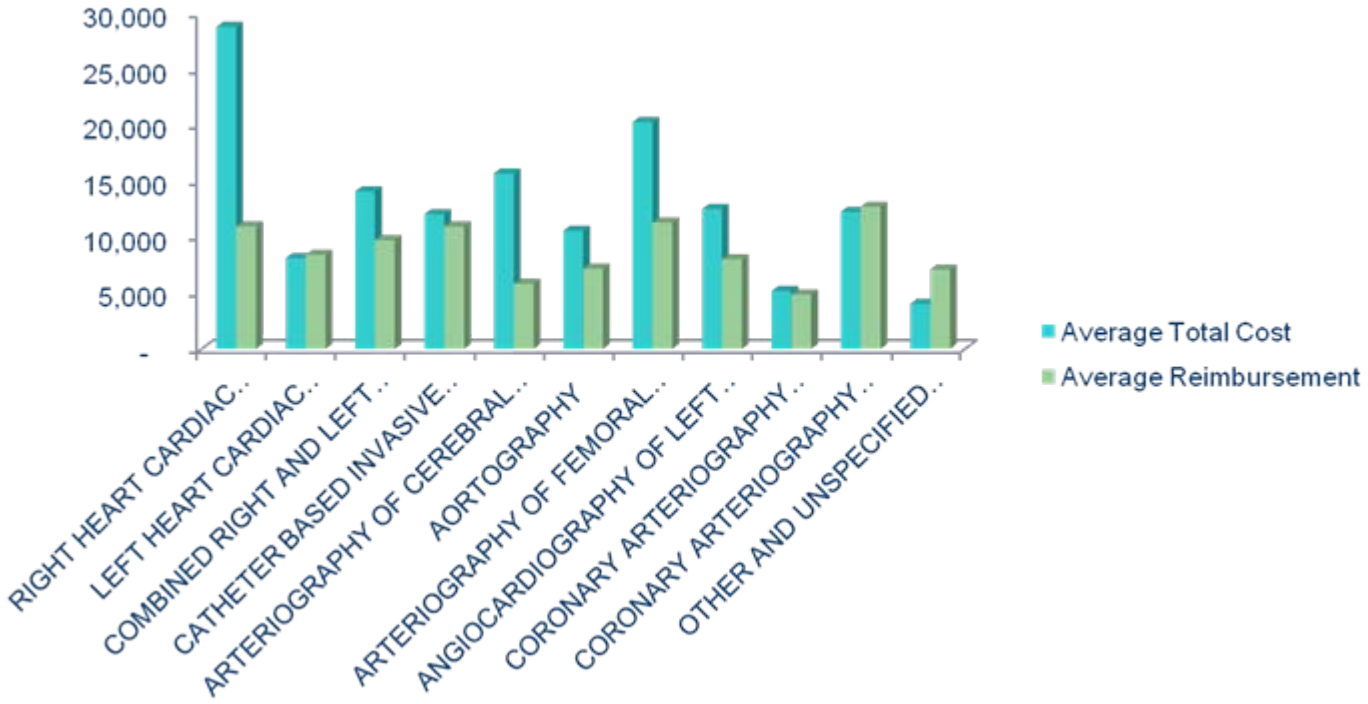
Diagnostic Services Comparison

Outpatient Cost and Reimbursement



Diagnostic Services Comparison

Inpatient Cost and Reimbursement

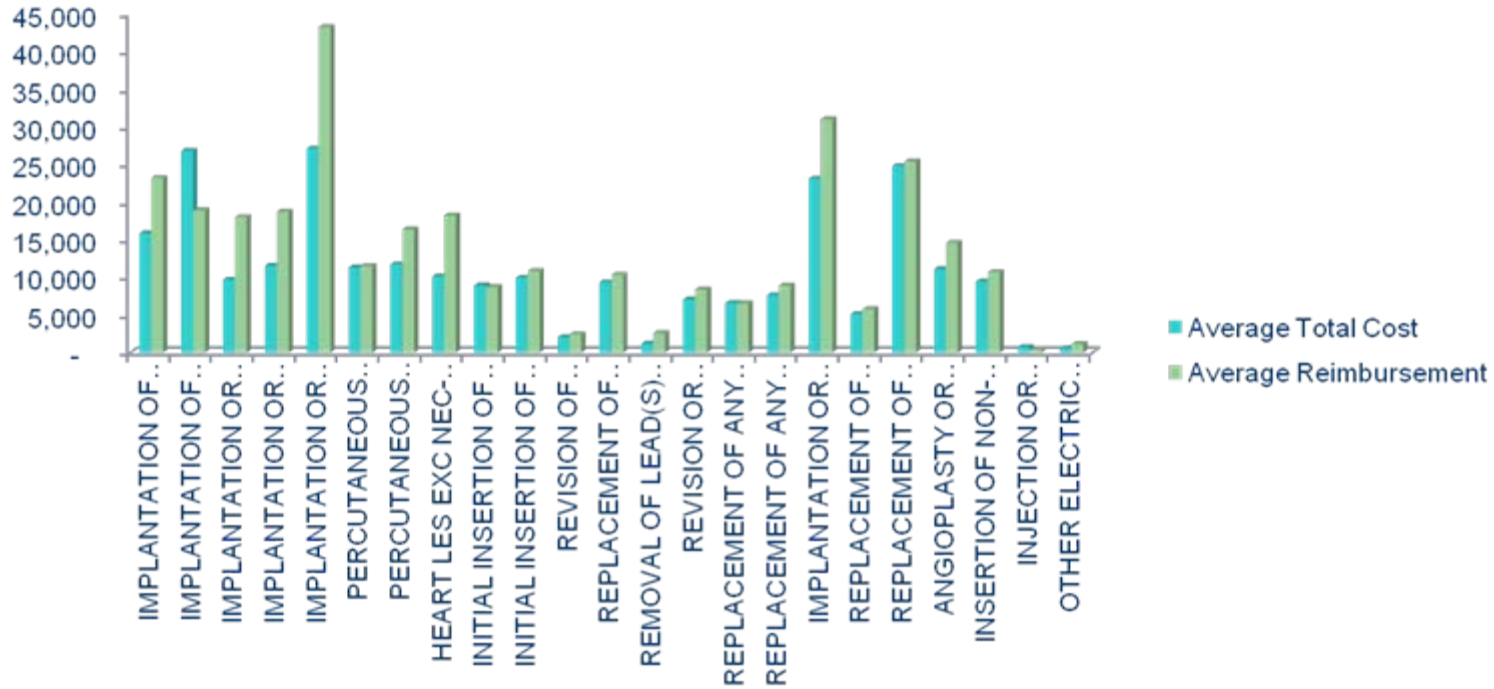


Therapeutic Services Comparison

- Average Total Cost for Procedures are $11,061
- Average Total Reimbursement is $12,784
- Inpatient procedures account for 42% of population
- Outpatient population is 58% of population
- Margin average on therapeutic population is <13%

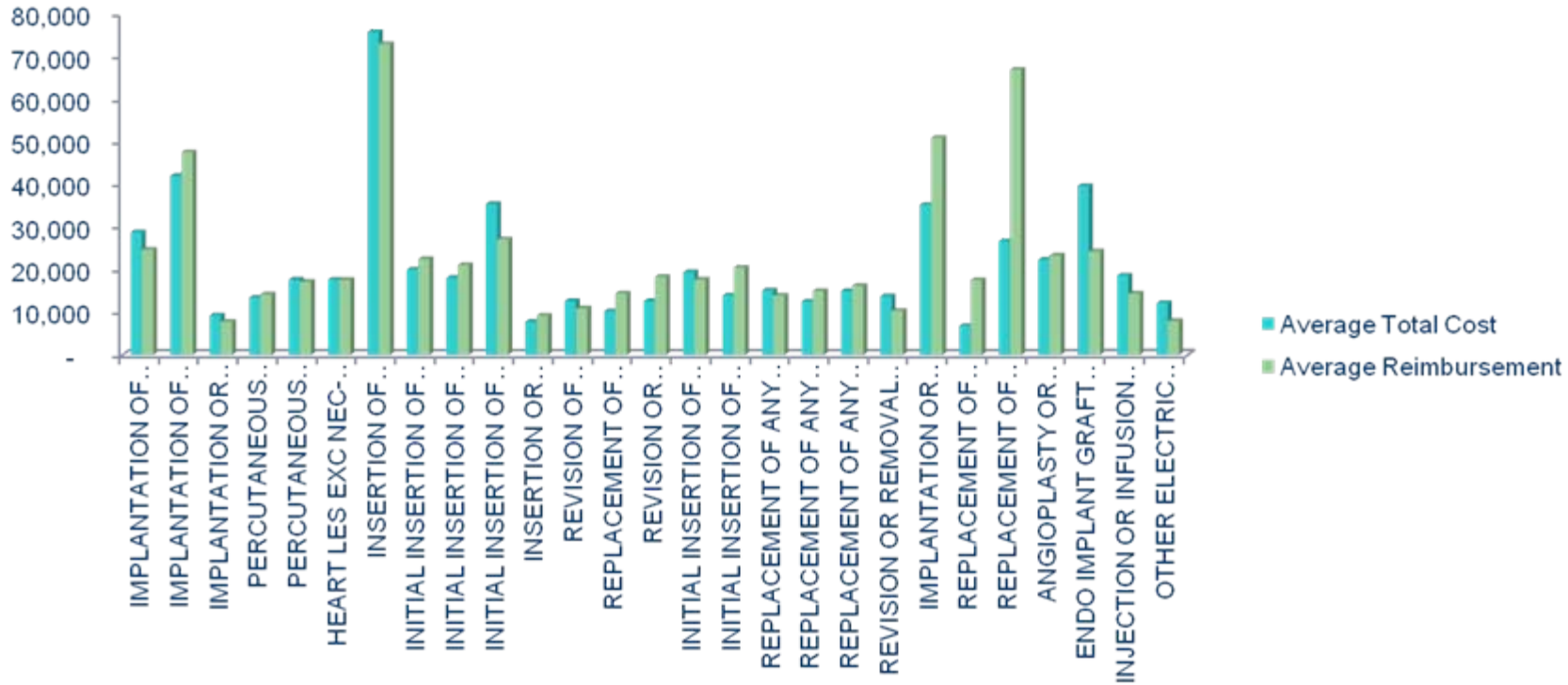
Theraputic Services Comparison

Outpatient Cost and Reimbursement



Theraputic Services Comparison

Inpatient Cost and Reimbursement



Equipment Expenses – Capital Expenditures

- Boston Scientific Instravascular Ultrasound (IVUS)
  - Critical to assess Left Main Disease & Borderline Coronary Lesions, Size Reference, Stent Depth
  - Capital Investment: $50,000 - $100,000
- Volcano S5/S5i Imaging System with IVUS and FFR
  - Rental Agreement
    - $5,000 per month for 6 months that goes toward purchase price of $120,000

Equipment Expenses – PCI Supplies Needed (Consignment)

- 6F & 7F Coronary Guiding Catheters.014 Coronary Guide Wires
- 185 cm & 300 cm Lengths
- Floppy
- Moderate Support
- Extra Support
- Coronary Balloons
  - OTW & Rx
  - Diameters: 1.5mm-6.0mm
  - Lengths: 6mm-20mm

Equipment Expenses – PCI Supplies Needed (Consignment)

- Coronary Stents
  - Bare Metal
    - Diameters: 2.25mm-5.0mm
    - Lengths: 8mm-32mm
- Drug Eluting Stents
  - Drugs: Paclitaxol & Everolimus
  - Diameters: 2.25mm-4.0mm
  - Lengths: 8mm-38mm

Average Reimbursement Per Procedure – Boston Scientific Data

- Diagnostic Heart Catheterization
  - Inpatient: $11,176
  - Outpatient: $2,727
- Primary PCI
  - Bare Metal Stent
    - Inpatient: $16,332
    - Outpatient: $5,656
- Drug Eluting Stent
  - Inpatient: $17,759
  - Outpatient: $7,279

*Payments Based on 2011 Medicare National Average Hospital Payment

Summary

- Margin average on diagnostic population is <12%
  - Cost to reimbursement ratio more favorable for Outpatient procedures
- Margin average on therapeutic population is <13%
  - Cost to reimbursement ratio more favorable for Outpatient procedures
    - Capital Investment in necessary equipment ranges from $50,000 to

Elective PCI w/out SOS

Draft Language

Definitions

PCI-Percutaneous coronary intervention

- Includes PTCA AND coronary stent implantation
- Does not include transcatheter valve, other structural heart disease procedures, left sided arrhythmia therapeutic procedures
- Facilities capable of elective PCI w/out SOS may also perform pacemaker, ICD procedures, right sided catheter ablation procedures, peripheral vascular angiography and therapeutic procedures
- Only cardiac surgery on-site facilities may perform structural heart disease, thoracic, abdominal aortic catheter procedures

Therapeutic cardiac catheterization service

- Means providing therapeutic cardiac catheterizations in an organized, regular basis in a laboratory to resolve anatomical and physiological heart problems
- Includes PCI, PTCA, atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker/ICD device implantations, transcatheter valve, other structural heart disease procedures, left sided arrhythmia therapeutic procedures
- Does not include intra coronary administration of drugs where only therapeutic intervention

Requirements for approval- Documentation for:

Attachment D

- Currently operating/applying to operate adult diagnostic cardiac catheterization service
- Minimum of two interventional cardiologists
  - Board Certified in Interventional Cardiology
  - Individual outcomes at least as good as national outcomes
  - Minimum of 300 PCIs performed since fellowship
  - Minimum of 100 PCIs in each of the most recent past 2 years
- Written agreement with open heart surgery facility that includes:
  - Involvement in credentialing criteria/recommendations for physicians to perform PCI
  - Ongoing cross-training for professional/technical staff involved in PCI provision
  - Ongoing cross-training for Emergency Department, Catheterization Laboratory and Critical Care Unit staff
  - Joint cardiology/cardiac surgery conferences
  - Development/ongoing review of patient selection criteria for PCI
  - Mechanism/protocols for patient transfers between facilities
  - Ability to transfer images electronically
  - Consultation on facilities, equipment, staffing, ancillary services, policies, procedures for PCI procedure provision
- Written protocol for case selection for performance of PCI consistent with current ACC and AHA practice guidelines
- Written policy/procedures established and maintained for training, staffing, and program review

Requirements for approval- Agreement to:

- Experienced nursing and technical catheterization laboratory staff
- Equipped catheterization laboratory with imaging systems, resuscitative equipment, IABP support, appropriate interventional equipment
- Competent cardiac care unit nurses in hemodynamic monitoring and IABP management
- Prompt and efficient PCI patient identification system
- Provide minimum of two physicians on call 24 hours per day and 365 days per year call schedule who are credentialed to perform primary PCI

Attachment D

Requirements for approval- Minimum PCI Volumes:

- Located within 1 hour drive time of existing PCI and/or Open Heart Surgery facility
  - Minimum of 350 PCIs performed in second 12 months of operation after initiation of the service and annually thereafter
  - CON revoked if less than 250 PCIs in second 12 months of operation or less than 350 PCIs in the third 12 months of operations
- Located more than 1 hour drive time from an existing PCI and/or Open Heart Surgery Facility
  - Minimum of 250 PCIs performed in the second 12 months of operation after initiation of the service and annually thereafter
  - CON revoked if less than 250 PCIs in the third 12 months of operations

Project delivery requirements if approved

- Report any changes in interventional cardiologists who perform PCI procedures
- Participation in benchmarked PCI data registry that includes:
  - Patient/clinical descriptions
  - Measures of outcomes
  - Measure of ACC appropriate use of procedure including SYNTAX or STS scores for each patient
  - Submission of all PCI cases
- Participation in and cost coverage for external impartial oversight body to publically report the following:
  - Complication rates
  - Number of procedures performed per operator
  - Success rates
  - Appropriate use rates
  - Patient transfer rates
- Patient consent forms notifying that the facility does not provide on-site open heart surgery and that transfer may be necessary
- Establish internal review board for report review of complication rates, morbidity and mortality data, success rates and the number of procedures performed and transferred
- Employ appropriate data management personnel
- Ensure minimum of 100 PCI procedures per year for each credentialed physician in the second 12 months after being credentialed and annually thereafter
- Credentialed PCI physicians must participate in institutional quality improvement program, be Board Certified in Interventional Cardiology, performed at least 300 PCIs since fellowship, complete at least 30 hours of CME directed toward interventional cardiology every 24 months
- Ensure Medical Director of the catheterization service performs PCIs annually

Documentation of projections

- Specification of how volume projections were developed including description of the data sources used, assessments of accuracy of these data, statistical method used to make the projections
- Physician commitments
  - PCI cases performed
  - Utilization of existing cardiac catheterization service in compliance with volume requirements for therapeutic cardiac catheterization
  - Continuation of compliance with volume requirements subsequent to the initiation of PCI service proposed by applicant
  - Cannot represent duplicate cases
  - Must report:
    - Name of physician that performed PCI cases to be transferred to the applicant cardiac catheterization service
    - Number of PCI cases each physician performed during the most recent 12-month period
    - Location(s) at which the PCI cases to be transferred were performed, including evidence that the existing location and the proposed location are within the same health service area.
    - Written commitment from each physician that he or she will perform at least the volume of PCI cases to be transferred to the applicant cardiac catheterization service for no less than 3 years subsequent to the initiation of the PCI service proposed by the applicant
    - Number of PCI cases performed, at the existing cardiac catheterization facility from which PCI cases will be transferred, during the most recent 12-month period prior to the date an application is submitted
- Documentation of existing patient transfers from applicant facility to existing PCI or Open Heart Surgery program that includes unique patient identifies, ICD-9 diagnosis code, facility where patient was transferred, physician patient transferred to, date of patient transfer

Draft Language for Elective PCI w/out SOS

Section 2. Definitions

(U) “PCI” MEANS PERCUTANEOUS CORONARY INTERVENTION INCLUDING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA)and coronary STENT implantation. THE TERM DOES NOT INCLUDE TRANSCATHETER VALVE, OTHER STRUCTURAL HEART DISEASE PROCEDURES, OR LEFT SIDED ARRHYTHMIA THERAPEUTIC PROCEDURES.
A FACILITY DESIGNATED AS ONE CAPABLE OF ELECTIVE PCI WITHOUT SOS MAY ALSO PERFORM PACEMAKER, ICD PROCEDURES, RIGHT SIDED CATHETER ABLATION PROCEDURES, AND PERIPHERAL VASCULAR ANGIOGRAPHY AND THERAPEUTIC PROCEDURES. STRUCTURAL HEART DISEASE PROCEDURES AND THORACIC AND ABDOMINAL AORTIC CATHETER PROCEDURES CAN ONLY BE PERFORMED IN A SITE HAVING CARDIAC SURGERY ON-SITE.

(z) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or physiological problems in the heart. The term includes, but is not limited to: percutaneous coronary intervention (PCI), percutaneous transluminal coronary angioplasty (PTCA), atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, or catheter ablation, ~~and~~ 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.

Section 5. Requirements for approval -- applicants proposing to initiate an adult diagnostic cardiac catheterization service with provision to perform PCI without on-site open heart surgery services

Sec. 5. (1) An applicant proposing to initiate PCI without on-site open heart surgery services shall submit documentation demonstrating all of the following:

(a) The applicant currently operates, or is applying to initiate, an adult diagnostic cardiac catheterization service.

(b) The interventional cardiologists (at least two) to perform the PCIs at the start of the program meet all of the following criteria:

(i) Board Certified in Interventional Cardiology

(ii) individual outcomes are at least as good as national outcomes (iii) performed at least 300 PCIs total since fellowship

(iv) performed at least 100 PCIs in each of the most recent past 2 years preceding the date the application was submitted to the Department.

(c) A written agreement with an open heart surgery facility, signed by senior executives for both facilities, that includes all of the following:

(i) Involvement in credentialing criteria and recommendations for physicians approved to perform PCI;

(ii) 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;

(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 PCI patient candidates; competency to be documented annually;

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

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

(vi) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for prompt medical or surgical care; Written protocols, signed by the applicant and the open heart surgery facility, must be in place, with provisions for the implementation for immediate and efficient transfer (transfer complete within 1 hour) of patients requiring surgical evaluation and/or intervention 24 hours per day, 365 days per year. The protocols shall be reviewed/tested on a regular (at least semi-annual) basis; and must include surgical consent being obtained by the transferring physician; and

(vii) Ability to transfer images electronically for the review of cases with the open heart surgery facility if needed;

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

(d) 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 CABG. 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.

(e) Written policy and procedures must be established and maintained for training, staffing, and program review.

(2) An applicant shall agree to all of the following:

(a) 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 surgery facility or at a Primary PCI facility; and participate in an un-interrupted 24-hour, 365-day call schedule, with competency documented annually.

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

(c) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management with competency documented annually.

(d) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid transfer from the Emergency Department to the Catheterization Laboratory must be developed and maintained so that door-to-balloon targets are met.

(e) Because primary PCI must be available to emergency patients 24 hours per day, 365 days a year, 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.

(3) An applicant shall project the following minimum PCI volumes:

(a) if located within 1 hour drive time of an existing PCI and/or Open Heart Surgery facility, a minimum of 350 PCIs will be performed in the second 12 months of operation after initiation of the service, and annually thereafter. The Department shall revoke a CON for a program that performs less than 250 PCIs in the second 12 months of operation, or less than 350 PCIs in the third 12 months of operation.

(b) if located more than 1 hour drive time from an existing PCI and/or Open Heart Surgery facility, a minimum of 250 PCIs will be performed in the second 12 months of operation after initiation of the service, and annually thereafter. The Department shall revoke a CON for a program that performs less than 250 PCIs in the third 12 months of operations.

(4) An applicant shall demonstrate that it meets the requirements of Section 14(2) for the number of PCIs projected under subsection (3).

Section 13. Project delivery requirements – additional terms of approval for applicants approved under Section 5

Sec. 13. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

(a) Shall immediately report to the Department any changes in the interventional cardiologists who perform the PCI procedures.

(b) Compliance with requirements of the standards set forth in Section 5.

(c) The applicant shall participate in a benchmarked PCI data registry designated by the Department which includes all of the following:

(i) Patient and clinical descriptions;

(ii) Measures of outcomes; and

(iii) Measure of the ACC appropriate use of the procedure including SYNTAX or STS score in each patient.

The Department or its designee shall require that the applicant submit data on all PCI cases. The applicant shall provide the required data in a format established by the designated registry. The applicant shall be liable for the cost of data submission. The Department shall require that the applicant submit a summary report on an annual basis which shall be made available to the public.

(d) The applicant shall participate in an external impartial oversight body to be designated by the Department. The applicant shall be liable for the cost of participating in this oversight process and must continue to participate annually thereafter. The oversight body shall produce an annual report of all PCI programs which will contain, at a minimum, all of the following:

(i) complication rates;

(ii) number of procedures performed per operator;

(iii) success rates;

(iv) appropriate use rates;

(v) patient transfer rates

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 public. All PCI programs performing less than 250 PCIs per year in any given year must have all cases reviewed by this oversight body for appropriateness and outcomes.

(e) An approved service shall include in their consent for PCI, notification to the patient that the facility does not provide on-site open heart surgery and that transfer to a facility providing open heart surgery may be necessary.

(f) An approved service shall establish an internal review body, including at a minimum the Chief Medical Officer, Director of Cardiovascular Services, Director of Cardiovascular Services for the facility identified in Section 5(1)(c), and Director of Open Heart Surgery for the facility identified in Section 5(1)(c) (or equivalent physician representatives), which shall receive and review at least annual reports describing the activities of the cardiac catheterization service including: complication rates (including emergency surgical procedures); morbidity and mortality data; success rates and the number of procedures performed and procedures requiring transfer.

(g) An approved service shall employ appropriate data management personnel to insure timely and accurate reporting to the registry and reviewing bodies described in subsections (c) and (d).

(h) Each physician credentialed by a hospital to perform PCI procedures shall perform, as the primary operator, a minimum of 100 PCI procedures per year in the second 12 months after being credentialed to perform procedures at the applicant hospital, and annually thereafter. The annual case load for a physician means PCI cases performed by that physician in any hospital or in any combination of hospitals. The applicant shall be responsible for reporting to the Department, on an annual basis, the name and the number of PCI procedures performed by each physician credentialed to perform PCI procedures. 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 PCIs total since fellowship
(iii) at least 30 hours of CME (continuing medical education) directed toward interventional cardiology every 24 months

(i)The medical director of the applicant catheterization service shall perform PCIs at the facility identified in Section 5(1)(c) annually. In addition, the medical director of the catheterization service for the facility identified in Section 5(1)(c) shall perform PCIs at the applicant facility during each year the applicant facility reaches minimum volume.

(j) The applicant shall always have in place a written agreement meeting all of the requirements of Section 5(1)(c) as long as they do not have an on-site open heart surgery program, but may change the entity with which they are contracted.

Section 14. Documentation of projections

Sec. 14. (1) An applicant required to project volumes of service under sections 4, 6, and 7 shall specify how the volume projections were developed. This specification of the projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

(2) An applicant required to project volumes of service under Section 5 shall utilize one or more of the following:

(a) physician commitments of PCI cases performed at an existing cardiac catheterization service and shall demonstrate, with documentation satisfactory to the Department, that the utilization of the existing cardiac catheterization service is in compliance with the volume requirements for therapeutic cardiac catheterization applicable to that service, and will continue to be in compliance with the volume

requirements applicable to that service subsequent to the initiation of the PCI service proposed by the applicant. The applicant also must demonstrate that the commitments do not represent duplicate cases with any of the cases identified in subsection (b). In demonstrating compliance with this subsection, an applicant shall provide each of the following:

(i) The name of each physician that performed PCI cases to be transferred to the applicant cardiac catheterization service.

(ii) The number of PCI cases each physician, identified in subdivision (a), performed during the most recent 12-month period for which verifiable data is available.

(iii) The location(s) at which the PCI cases to be transferred were performed, including evidence that the existing location and the proposed location are within the same health service area.

(iv) A written commitment from each physician, identified in subdivision (a), that he or she will perform at least the volume of PCI cases to be transferred to the applicant cardiac catheterization service for no less than 3 years subsequent to the initiation of the PCI service proposed by the applicant.

(v) The number of PCI cases performed, at the existing cardiac catheterization facility from which PCI cases will be transferred, during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable annual survey data is available.

(b) Existing patient transfers from the applicant facility to an existing PCI or Open Heart Surgery program for purposes of receiving a PCI at that facility. In demonstrating compliance with this subsection, an applicant shall provide each of the following, for each patient transfer in the previous 12 months:

(i) Unique patient identifier.

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

(iii) Facility where the patient was transferred.

(iv) Physician patient transferred to.

(v) Date of patient transfer.

(c) Existing PCI cases performed at the applicant facility in the most recent 12 months for which verifiable data is available to the Department.

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.
- Item I- added new elective PCI definition
- Item (k)- moved to Section 5
- Item (o)- moved to section 3
- Item Q- modified definition to include transcatheter valves, other structural heart disease procedures, and left sided arrhythmia procedures.
- Item(s) (e), (m), (s)- deleted as mobile services are not utilized in Michigan
- Item (x)- moved to Section 4

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.
- Added subsection 5 outlining requirements to initiate elective PCI without on-site open heart surgical services.
- The Department has NOT modified the methodology for initiation.

Section 4- Replace Existing Cardiac Catheterization Service

- 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.
- 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.

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.

Section 6- Acquire a Cardiac Catheterization Service

- Added acquisition definition based on PET language.
- Added acquisition language based on Open Heart Surgery Standards.

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.

Section 9- Methodology

- The Department deleted language under subsection 2 to allow for the counting of peripheral catheterizations under initiation and expansion. 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.
- 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.