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

Thursday March 10, 2011

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

APPROVED MINUTES

I. Call to Order

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

A. Members Present:

Fouad Ashkar, Garden City Hospital
Bart Berndt, Lakeland Regional Medical Center
Barton Buxton, Ed.D, Lapeer Regional Medical Center
David Dobies, MD, Genesys Regional Medical Center
Kevin Donovan, Muskegon Construction
Basil Dudar, MD, FACC, Beaumont Hospitals
Kim Eagle, MD, Chairperson, University of Michigan Health System
Robert Goodman, MD, MHSA, FACEP, Blue Cross Blue Shield/Blue
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 via conference call
Dagmar Raica, Marquette General Health System
Arthur L. Riba, MD, Oakwood Healthcare, Inc.
Theodore Schreiber, MD, Detroit Medical Center
Frank D. Sotille, MD, Crittenton Hospital Medical Center
Douglas W. Weaver, MD, Henry Ford Health System
Lawerence O. Wells, Michigan League for Human Services

B. Michigan Department of Community Health Staff present:

Jessica Austin
Sallie Flanders
William Hart Jr.
Larry Horvath arrived @ 10 :35 a.m.

Natalie Kellogg
Brenda Rogers
Tania Rodriguez

II. Declaration of Conflicts of Interests

No conflicts of interests declared.

III. Review of Minutes

Motion by Mr. Buxton and seconded by Dr. Dobies to accept the minutes as presented. Motion carried in a vote of 19- Yes, 0- No, and 0- Abstain.

IV. Review of Agenda

Motion by Mr. Buxton and seconded by Dr. Dobies to accept the agenda as modified with one addition to Item IX to include Angioplasty fraud discussion. Motion carried in a vote of 19-Yes, 0-No, and 0-Abstain.

V. Presentation and Further Discussion of Equivalents

Dr. Lewis gave a verbal and written presentation on "Simplifying the Reporting Requirements for Expansion of Labs." (See Attachment A)

Discussion followed.

VI. Potential Costs of Cardiac Cath Lab Expansion to Include PCI Without Surgical Backup in MI Hospitals

Dr. Dobies gave a brief presentation on "Potential Costs of CC Lab Expansion Sub-Committee." (See Attachment B)

Discussion followed.

Chairperson Eagle suggested Dr(s). Dobies, Riba, and Mr. Buxton present the SAC with consensus opinions of state-wide costs for elective PCI without on-site surgical back-up. Specifically, the reimbursement rates for actual cost or charge per case and reimbursement per case.

Break @ 10:45 a.m. - 11:00 a.m.

VII. Potential Draft Language for Elective PCI Without On-site Surgical Backup

Dr. Weaver gave a brief presentation on "Draft Language Elective PCI Without On-Site Surgical Backup." (See Attachment C)

Discussion followed.

Larry Horvath gave an overview of enforcement and discussion continued.

Chairperson Eagle suggested Dr(s). Dobies, Schreiber, Weaver, and Larry Horvath continue working on draft language.

VIII. Report & Discussion on Diagnostic Volumes

Dr. Pielsticker gave a brief overview on "Current Cardiac Cath CON Standards and Proposed Changes" including a brief summary on scientific data as it relates to the current Standards. (See Attachment D).

Discussion followed.

Chairperson Eagle suggested Dr(s). Pielsticker, Dobies, and Mr. Horvath collaborate and produce draft language on volume replacement and primary PCI.

Motion by Dr. Pielsticker and seconded by Mr. Buxton to drop volume requirements for replacement. Motion carried in a vote of 16-Yes and 3- No.

IX. Angioplasty Fraud Article (See Attachment E)

Chairperson Eagle provided a brief summary on the article "Forbes Regional to Check 2 Cardiologists' Fitness."

Discussion followed.

Motion by Dr. Pielsticker and seconded by Mr. Buxton to include and count peripherals for initiation and expansion. Motion carried in a vote of 15- Yes, 0- No, and 2-Abstain.

X. Public Comment

Dennis McCafferty, Economic Alliance for Michigan (EAM), (See Attachment F)
Barb Jackson, Blue Cross Blue Shield of MI
Bob Meeker, Spectrum Health

XII. Next Steps and Future Agenda Items

A. Dr(s). Lewis, Dobies, and Schreiber will provide further information on volume requirements.

B. Dr(s). Dobies, Riba, Schreiber and Mr. Buxton will present the SAC with detailed information regarding cost and financial analysis.

C. Dr(s). Weaver, Schreiber, and Mr. Horvath will prepare a recommendation for draft language for elective PCI without open heart surgery backup and present at the next meeting.

D. Dr(s). Pielsticker, Dobies, and Mr. Horvath will review primary PCI.

E. The Department will draft language consistent with the votes and outcome of the March 10, 2011 CC SAC.

XIII. Future Meeting Dates

A. April 6, 2011 (possible reschedule)
B. May 4, 2011 (if needed)

XIV. Adjournment

Motion by Mr. Buxton and seconded by Mr. Wells to adjourn the meeting @ 1:09 p.m. Motion carried.

Simplifying the Reporting Requirements for Expansion of Labs

Expansion of Cath Labs in Michigan

- Current Requirements:
  - Need 1,500 procedure equivalents to expand
  - Lab needs to do 1,000 procedure equivalents(full utilization) by year 2

- A full time lab of 1,000 procedure equivalents is:
  - 1,000 diagnostic caths/year, or 4.5 daily, or
  - 667 PCI's/year, or 3.0 daily

- To expand under the current regulations would require:
  - 7 diagnostic caths or 4 – 5 PCI's daily in the lab

- Using the 1,000 PE per lab in Michigan and comparing this to the PEs reported at each hospital, many are way off:
  - Too many labs at some sites
  - 17 hospitals show requirement of 5 or more than what they currently have
  - 3 show a need for 15 or more than what they have

The current process is flawed!

Rationale for a Simpler—Patient-based System

- The yearly capacity for a full time lab (conservative):
  - 8 hr x 220 business days
  - 176 hr/week

To be conservative, applicants can count all cases outside regular hours, balanced by time used for repairs/maintenance, holidays, vacations, etc.

If the threshold is set at 80%, or 6.5 hr/day:

- Capacity is 1,400 hr/year
- If exceed, can expand

Based on times in the survey, we now have two buckets:

Simplicity!	
LHC	1.5 hrs
All diagnostic caths	
Cardioversions	
Biopsies	
PCI	2.7 hrs
All	
Peripherals	2.7 hrs
All	
Pacer	2.7 hrs
Implant	
Generator change	
ICD/BiV	
Ablation	2.7 hrs
Right/left	
Newer Procedures	
Deferred	
Work in progress	
Next SAC	

Current Cardiac Cath CON Standards and Proposed Changes

Liz Pielsticker, MD
Ted Schreiber, MD
Dave Dobies, MD
Bart Buxton, Ed.D

March 10, 2011

Cardiac Cath Services Charge #1

- Whether or not cardiac catheterization services should continue to be regulated. If regulation of this service should be maintained, make recommendations, if necessary, regarding any modifications to the requirements.

Current CON Standards

- **Section 3. Requirements for approval -- all applicants**

  (1) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory located within a hospital, and have within, or immediately available to the room, dedicated emergency equipment to manage cardiovascular emergencies. NO CHANGE

  (2)An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. An applicant that is initiating a new service or is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved. NO CHANGE

Current CON Standards

- **Section 4. Requirements for approval -- applicants proposing to initiate an adult diagnostic cardiac catheterization service**

- **(1) An applicant proposing to initiate an adult diagnostic cardiac catheterization service shall project a minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterization will be performed in the second 12 months of operation after initiation of the adult diagnostic cardiac catheterization service, and annually thereafter.**

2001 ACC/SCAI Clinical Expert Consensus Guidelines for Cath

- The use of a specific minimum number of cases to define the quality of operator performance is obviously fraught with problems.... Given the low risk for diagnostic cardiac catheterization, the Committee could not arrive at any consensus as to what would constitute a minimum workload for individuals with regard to diagnostic procedures. There have been no data to justify the prior recommendation of at least 150 cases/year (5). The minimum diagnostic caseload for the entire laboratory also varies widely from state to state, often depending on the presence of the certificate of need (CON) process or other occasionally arbitrary requirements. It falls upon the director of the laboratory to ensure that all studies in the cardiac catheterization laboratory are of the highest quality. In general, high-volume laboratories have consistently been shown to have fewer complications than low-volume facilities, although quality cannot be deciphered by observing the total laboratory volume alone (2).

J Am Coll Cardiol, 2001; 37:2170-2214

Current CON Standards

- (2)An applicant proposing to initiate an adult diagnostic cardiac catheterization service in a new single laboratory shall project the following volume of procedure equivalents, as applicable, will be performed in the second 12 months of operation after initiation of the service, and annually thereafter:

- (a) For a hospital located in a rural or micropolitan statistical area county, a minimum of 500 procedure equivalents which shall include the 300 procedure equivalents in the category of adult diagnostic cardiac catheterization required under subsection (1).

- (b)For a hospital located in a metropolitan statistical area county, a minimum of 750 procedure equivalents which shall include the 300 procedure equivalents in the category of adult diagnostic cardiac catheterization required under subsection (1). NO CHANGE

Current CON Standards

- (3)An applicant proposing to initiate an adult diagnostic cardiac catheterization service in 2 or more laboratories shall project that a minimum of 1,000 procedure equivalents per laboratory will be performed in the second 12 months of operation after initiation of the service, and annually thereafter. The projected volume shall include the procedure equivalents required by subsection (1). NO CHANGE

Current CON Standards

- **Section 6. Requirements for approval -- applicants proposing to initiate a pediatric cardiac catheterization service**

- **(1) An applicant proposing to initiate a pediatric cardiac catheterization service at a hospital that will perform cardiac catheterization procedures is required to have each of the following as outlined in the American Academy of Pediatrics (AAP), Guidelines for Pediatric Cardiovascular Centers (March 2002):**

  (a)a board certified pediatric cardiologist with training in pediatric catheterization procedures to direct the pediatric catheterization laboratory;

  (b) standardized equipment as outlined in AAP guidelines publication;

  (c) on-site ICU as outlined in AAP guidelines publication; and

  (d) on-site pediatric open heart surgery. **NO CHANGE**

Current CON Standards

- **Section 6. Requirements for approval -- applicants proposing to initiate a pediatric cardiac catheterization service**

- (2)An applicant proposing to initiate a pediatric cardiac catheterization service at a hospital that currently performs cardiac catheterization procedures shall project that a minimum of 600 procedure equivalents in the category of pediatric cardiac catheterizations will be performed in the second 12 months of operation after initiation of the pediatric cardiac catheterization service, and annually thereafter NO CHANGE

Current CON Standards

- Section 8. Requirements for approval -- applicants proposing to replace/upgrade cardiac catheterization laboratories

- (1) An applicant, other than a hospital that provides only pediatric cardiac catheterization services, proposing to replace/upgrade its only laboratory, shall demonstrate that it meets each of the following, as applicable:

- (a) For a hospital located in a rural county:

- (I) A minimum of 500 procedures equivalents were performed in the applicant's cardiac catheterization laboratory during the most recent 12 months of normal operation preceding the date the application was submitted to the Department; and

- (ii) A minimum of 500 procedure equivalents will be performed in the applicant's cardiac catheterization laboratory in the first 12 months of operation after installation of the new equipment, and annually thereafter. DISCUSSION

Current CON Standards

- b) For a hospital located in a non-rural county:
- (i) A minimum of 750 procedure equivalents was performed in the applicant's cardiac catheterization laboratory during the most recent 12 months of normal operation preceding the date the application was submitted to the Department; and
- (ii) A minimum of 750 procedure equivalents will be performed in the applicant's cardiac catheterization laboratory in the first 12 months of operation after installation of the new equipment, and annually thereafter. NO CHANGE

Current CON Standards

- (2)If an applicant is a hospital that provides only pediatric cardiac catheterization services proposes to replace/upgrade an existing cardiac catheterization laboratory, an applicant shall demonstrate that it meets each of the following:

- (a)A minimum of 500 procedure equivalents was performed in the applicant's cardiac catheterization laboratory in the most recent 12 months of normal operation preceding the date the application was submitted to the Department; and(b)A minimum of 500 procedure equivalents will be performed in the applicant's cardiac catheterization laboratory in the first 12 months of operation after installation of the new equipment, and annually thereafter. PROPOSE CHANGING TO 600, SAME AS INITIATE

Current CON Standards

- (3)An applicant with 2 or more laboratories proposing to replace/upgrade any of its laboratories shall demonstrate that it meets each of the following, as applicable:

- (a) An average of 1,000 procedure equivalents per room was performed in each existing cardiac catheterization laboratory in the hospital during the most recent 12 months of operation preceding the date the application was submitted to the Department, and

- (b) A minimum of 1,000 procedure equivalents will be performed in each cardiac catheterization laboratory in the first 12 months of operation after installation of the new equipment, and annually thereafter. NO CHANGE

Current CON Standards

- (4)An applicant proposing to replace equipment shall demonstrate that the existing equipment to be replaced is fully depreciated according to generally accepted accounting principles, or can clearly demonstrate that the existing equipment poses a threat to the safety of the public, or offers significant technological improvements which enhance quality of care, increases efficiency, and/or reduces operating costs. NO CHANGE

Current CON Standards

- (5)If an application involves the replacement/upgrade of equipment used by a mobile cardiac catheterization network, an applicant shall demonstrate both of the following:

- (a) At least 500 procedure equivalents were performed in the most recent 12 months of normal operation preceding the date the application was submitted to the Department; and

- (b)A minimum of 500 procedure equivalents will be performed in the first 12 months of operation after installation of the new equipment, and annually thereafter.

- (c) In evaluating compliance with subsections (a) and (b), the Department shall consider the combined utilization for all approved host facilities NO CHANGE - -NOT IN DRAFT ? NOT APPROVING

Current CON Standards

- **Section 9. Requirements for approval -- applicants proposing to expand a cardiac catheterization service by adding a laboratory**

- **(1)An average of 1,500 procedure equivalents per room per year was performed in each existing cardiac catheterization laboratory in the hospital during the most recent 12-month period preceding the date the application was submitted to the Department.**

- **(2)An average of 1,000 procedure equivalents will be performed in each cardiac catheterization laboratory (both existing and proposed) in the second 12 months of operation after initiating operation of the additional room, and annually thereafter. NO CHANGE**

Current CON Standards

- Section 10. Requirements for approval -- applicants for a mobile cardiac catheterization network

- (1)An application will not result in an increase in the number of mobile cardiac catheterization networks with valid CON approval as of the effective date of these standards.

- (2)An application will not result in an increase in the number of host facilities being served by a mobile cardiac catheterization network from the number of host facilities authorized to be served by that same network as of the effective date of these standards. ~~NO CHANGE~~

Current CON Standards

- (3)An application does not involve the initiation of a mobile cardiac catheterization network not authorized by a valid CON as of the effective date of these standards.

- (4)An application involving the provision of mobile cardiac catheterization services shall demonstrate that cardiac catheterization procedures will be performed within a hospital. The Department shall consider procedures performed in a mobile cardiac catheterization unit as within a hospital if the mobile unit is or will be physically adjoined to the hospital by means of a connector such that patients will not be transported outside the hospital in order to receive cardiac catheterization services. NO CHANGE

Current CON Standards

- **Section 11. Methodology for computing cardiac catheterization equivalents – procedures and weights**

- **(1) The following procedure equivalents shall be used in calculating and evaluating utilization of a cardiac catheterization laboratory:**

	ADULT	PEDIATRIC
DIAG CATH	1.0	3.0
THERAPEUTIC 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

Current CON Standards

- (2)For purposes of evaluating whether an applicant meets applicable volume requirements set forth in these standards, cardiac catheterization procedures per laboratory must be met exclusive of the intra- vascular catheterization procedures when considering expansion or replace/upgrade. The peripheral non-cardiac procedures shall count toward the total volume requirements for procedures, but the minimum volumes remain the same for initiation of cardiac catheterization services.

- WOULD LIKE TO SEE PERIPHERAL PROCEDURES COUNT TOWARD MINIMUM VOLUME REQUIREMENTS FOR INITIATION/UPGRADE/REPLACEMENT

In Summary

- Pediatric cath lab replace/upgrade requirements increase to 600 procedural equivalents, same as required for initiate
- Mobile cath lab provisions eliminated
- Peripheral equivalents be counted toward minimum volume requirements

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 C

- 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:

Attachment C

- 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 C

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

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.

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.

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.

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.

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

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.

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)

New Procedures continued…

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

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

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)

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

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)

Questions & Answers

Thank You.

Attachment E

PITTSBURGH TRIBUNE-REVIEW

Forbes Regional to check 2 cardiologists' fitness

By Luis Fabregas and Andrew Conte
PITTSBURGH TRIBUNE-REVIEW
Friday, March 4, 2011

Forbes Regional Hospital in Monroeville plans a thorough review of the qualifications of two cardiologists practicing there after resigning from Westmoreland Hospital amid findings they implanted coronary stents in at least 141 patients that may have been unnecessary.

Drs. Ehab Morcos and George Bousamra received temporary privileges several weeks ago to practice at Forbes, which is standard practice before new physicians get full privileges, said spokesman Dan Laurent. He would not say how many stent procedures the doctors performed there or whether Forbes officials will examine whether the implants were necessary.

Morcos, 48, of Export and Bousamra, 45, of Marshall resigned from the Westmoreland medical staff Jan. 12 after the first of two reviews by nationally recognized interventional cardiologists concluded that 141 patients received coronary stents that may not have been needed. The reviews, voluntarily contracted by the hospital, involved all 753 stent procedures done by the two doctors in 2010. Results of a review of their 2009 cases are expected by May, hospital officials told the Tribune-Review in a story first reported Thursday.

Officials at Excela Health, Westmoreland's Greensburg-based parent, said yesterday that 30 of the 141 patients have been referred to a medical liaison. Ten of them have scheduled appointments with their personal physicians, said Excela spokesman Alan Taylor. A call center established at the hospital received 56 calls.

"We would like to apologize to the patients who received coronary stents that may not have been necessary," Excela CEO Robert Rogalski said at a news conference held yesterday at the hospital. "We felt a strong moral and ethical duty to notify those involved and the community."

Continued attempts to reach the doctors and their attorneys were unsuccessful. Karen Piazza, manager at Westmoreland County Cardiology, said both doctors are still members of the Greensburg-based practice. She would not say whether the doctors are still treating patients and would not discuss their whereabouts.

"We will make a comment, but at this point all I can say is they are still part of the group," Piazza said.

Morcos had privileges to practice at UPMC Mercy, Uptown, where he has

performed two stent procedures since 2008, said UPMC spokesman Paul Wood. Cardiac specialists at Mercy are reviewing all of Morcos' cases, including eight that did not involve stent placement. His privileges at Mercy have been suspended pending the review's completion, Wood said.

About 60 to 70 percent of the patients who received the stents at Westmoreland are covered by Medicare, the federal program that helps pay medical bills for those age 65 and older. Rogalski estimated Westmoreland is reimbursed about $10,000 for each of those cases. That figure is in the lower range of payments made by Medicare for the procedures nationwide. The agency pays half of U.S. hospitals at least $9,664 to $17,332 for stent implants.

Highmark Inc., the region's largest insurer, would not say how much it pays Westmoreland Hospital or its cardiologists for stent placements. Spokesman Michael Weinstein issued a statement, saying the insurer would be "reaching out to discuss this matter" with hospital administrators to "better understand the impact, if any, on Highmark members, and to understand the specific corrective actions the health system is planning to take."

Officials said the affected patients received one of two types of stents: a drug-eluting device or a bare metal version. Both types expand to open arteries to the heart that are clogged with plaque. Dr. Jerome Granato, Excela's chief medical officer, said the stents are not foolproof, because regrowth of tissue can reclog 5 to 10 percent of the drug-coated stents and 30 to 40 percent in the metal stents.

Most physicians recommend treating diseased arteries with stents when the blockage is greater than 70 percent. Westmoreland officials said the 141 patients had blockages of less than 50 percent. Some stents were inserted in patients who had as little as 10 percent blockage, Granato said.

Dr. Jeffrey Moses, director of the cardiac catheterization laboratory at New York-Presbyterian Hospital, said blockage of as little as 40 percent can interfere with blood flow to the heart. Moses said it is crucial for doctors to conduct supplemental tests such as stress tests to determine whether the blockage is critical.

"It's not just a matter of a 50 percent blockage," he said. "If a person had symptoms and abnormal stress test in the area of blockage, I still think you can make the case that it may not have been inappropriate."

Medicare payments for stent procedures topped $3.4 billion in 2008, according to the American College of Cardiology, a nonprofit medical society that has developed standards to prevent unnecessary stent placement. The college has called for accreditation of catheterization laboratories and better standards for when to use coronary stents.

The way hospitals and doctors are paid, however, often contradict those standards, said Amy Murphy, the college's spokeswoman.

"You're not paid for the quality of care; you're paid for the procedure," she said. "It's a flawed system, based on the number of procedures. ... We do all this quality work, but the way people are paid is in direct contrast to that."

Stent use has declined by as much as 25 percent in recent years, Moses said, because some doctors choose to treat patients with drugs such as statins, which improve cholesterol levels.

"The pendulum is swinging in some areas too far in the other direction, and people are being deprived of this very valuable therapy," he said.

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