

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

Wednesday June 18, 2014

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

APPROVED MINUTES

I. Call to Order

Chairperson Turner-Bailey called the meeting to order at 9:35 a.m.

A. Members Present:

Renee Turner-Bailey, Chairperson, International Union, UAW
Luay Alkotob, MD, Hurley Medical Center
Duane DiFranco, MD, Blue Cross Blue Shield of MI
Georges Ghafari, MD, Beaumont Health System
Ginny Latty, Covenant Healthcare
Brahmajee Nallamothe, MD, University of Michigan Health System
Meg Pointon, UAW Retiree Medical Benefits Trust
Fadi Saab, MD, Metro Hospital
Frank Tilli, MD, Genesys Regional Medical Center
Douglas Weaver, MD, Henry Ford Health System
David Wohns, MD, Spectrum Health
Karen Yacobucci, Allegiance Health

B. Members Absent:

None.

C. Michigan Department of Community Health Staff present:

Tulika Bhattacharya
Sallie Flanders
Natalie Kellogg
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Introduction of Members & Staff

Introductions were made.

III. Declaration of Conflicts of Interests

Ms. Rogers gave a brief summary of the declaration of conflicts of interests (see Attachment A).

No conflicts were declared.

IV. Review of Agenda

Motion by Dr. DiFranco and seconded by Dr. Weaver to approve the agenda as presented. Motion Carried.

V. Basic CON Review

Ms. Rogers gave a brief review of the CON Process (see Attachment B).

VI. Overview of Current CC Programs in Michigan

Ms. Bhattacharya gave a brief overview of the current data from the CON Annual Survey (see Attachment C).

VII. Review and Discussion of Charge

Chairperson Turner-Bailey gave a brief overview of the charge (see Attachment D).

VIII. Background Material

Chairperson Turner-Bailey explained any data or information that SAC members feel would be appropriate to share can be disseminated through the Department to the rest of the SAC members.

IX. Public Comment

None.

X. Next Steps and Future Agenda Items

Chairperson Turner-Bailey advised the SAC members to think about the sub-committee(s) members would be interested in volunteering or serving on.

XI. Future Meeting Dates - August 14, 2014, September 10, 2014, October 8, 2014, November 6, 2014, and December 17, 2014.

Dr. Tilli volunteered to send the Journal of the American College of Cardiology (JACC) June 2014, Volume 63, Issue 23, citing updated information on primary PCI.

The CCSAC members developed sub-committees, as follows:

Science and prevalence sub-committee members: Dr. Alkotob, Dr. Wohns, and Dr. Ghafari.

Quality and access sub-committee members: Dr. Alkotob, Ms. Pointon, Ms. Yacobucci, Ms. Latty, Dr. DiFranco, and Dr. Wohns.

Cost sub- committee members: Dr. DiFranco, Dr. Saab, Dr. Weaver, Dr. Nallamothu, and Ms. Pointon.

The Department was asked to clarify the intent of the language in Charge 1 with CON Commission Chairperson Keshishian.

XII. Adjournment

Motion by Dr. Nallamothu and seconded by Dr. Alkotob to adjourn the meeting at 11:15 a.m. Motion Carried.

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

B. Definition - Conflict of Interest

1. Under the State Ethics Act, 1973 PA 196, MCL 15.341, et seq, and in accordance with the Advisory Opinion of the State Board of Ethics of November 5, 2004, a conflict of interest for Commission members exists when the individual member has a financial or personal interest in a matter under consideration by the Commission. The personal interest of a Commission member includes the interest of the member's employer, even though the member may not receive monetary or pecuniary remuneration as a result of an adopted CON review standard.
2. A Commission member does not violate the State Ethics Act if the member abstains from deliberating and voting upon the matter in which the member's personal interest is involved.
3. A Commission member may deliberate and vote on matters of general applicability that do not exclusively benefit certain health care facilities or providers who employ the Commission member, even if the matter involves the member's employer or those for whom the member's employer does work.
4. Deliberating includes all discussions of the pertinent subject matter, even before a motion being made.

C. Procedures - Conflict of Interest

1. A Commission member must disclose any potential conflict of interest after the start of a meeting, when the Commission begins to consider a substantive matter, or, where consideration has already commenced, when a conflict or potential conflict of interest becomes apparent to the member.
2. After a meeting is called to order and the agenda reviewed, the chairperson must inquire whether any Commission member has a conflict or potential conflict of interest with regard to any matters on the agenda.
3. A Commission member who is disqualified from deliberating and voting on a matter under consideration due to a conflict of interest may not be counted to establish a quorum regarding that particular matter.
4. Where a Commission member has not discerned any conflict of interest, any other Commission member may raise a concern whether another member has a conflict of interest on a matter. If a second member joins in the concern, the Commission must discuss and vote on whether the member has a conflict of interest before continuing discussion or taking any action on the matter under consideration. The question of conflict of interest is settled by an affirmative vote of a majority of those Commission members appointed and serving, excluding the member or members in question.
5. The minutes of the meeting must reflect when a conflict of interest had been determined and that an abstention from deliberation and voting had occurred.

Basics of Certificate of Need
(CON)
CC SAC
June 18, 2014



Certificate of Need Federal Background

Attachment B

- The District of Columbia and New York developed CON programs in 1964 in an effort to contain rising health care costs.
- Federally mandated CON programs were established in 1974 as a national health care cost containment strategy.



Certificate of Need Federal Background

Attachment B

- The federal mandate for CON was not renewed by the U.S. Congress in 1986.
- CON regulations are structured, in principle, to improve access to quality health care services while containing costs. Health care organizations are required to demonstrate need before investing in a regulated facility, service or equipment.

Michigan CON Background Attachment B

- Public Act 368 of 1978 mandated the Michigan Certificate of Need (CON) Program.
- The CON Reform Act of 1988 was passed to develop a clear, systematic standards development system and reduce the number of services requiring a CON.

CON Commission

- Members appointed by Governor
 - Three year terms
 - No more than six from either political party
 - Responsible for developing and approving CON review standards w/legislative oversight
- Public Act 619 of 2002 made several modifications.
 - Expanded the Commission from 5 to 11
 - Key stakeholders are now represented on the Commission (e.g., physicians)

What is Covered by the CON Program?

Attachment B

The following projects must obtain a CON:

- Increase in the number or relocation of licensed beds
- Acquisition of an existing health facility
- Operation of a new health facility
- Initiation, replacement, or expansion of covered clinical services



Capital expenditure projects (i.e., construction, renovation) must obtain a CON if the projects meet the following threshold:

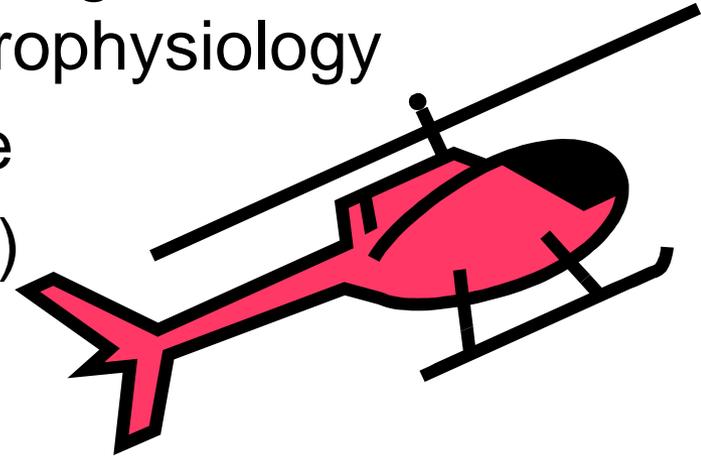
- \$3,160,000 for clinical service areas (January 2014)

Note: Threshold is indexed annually by the Department based on the Consumer Price Index.

Categories That Require CON Approval

Attachment B

- Air ambulances (helicopters)
- Cardiac catheterization, including diagnostic, therapeutic, angioplasty, and electrophysiology
- Hospital beds – general acute care
- Magnetic resonance imaging (MRI)
- Megavoltage radiation therapy
- Neonatal intensive care units
- Nursing home/hospital long-term care beds
- Urinary lithotripters



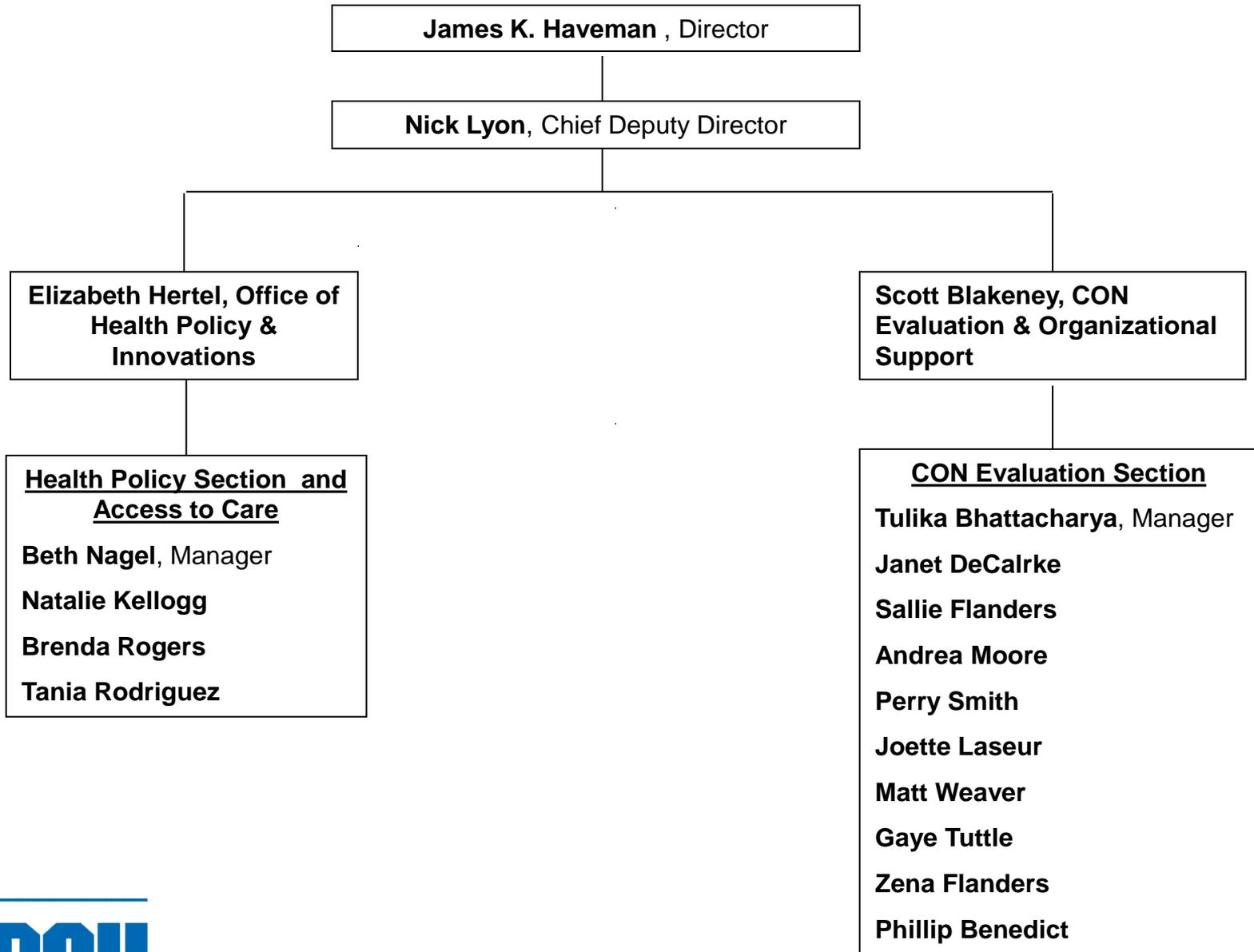
Categories That Require CON Approval

Attachment B

- Open heart surgery
- Positron Emission Tomography (PET)
- Psychiatric beds – acute inpatient
- Surgical services – hospital and free-standing
- Transplantation services – bone marrow, including peripheral stem cell, heart-lung, and liver
- Computed tomography (CT) scanners

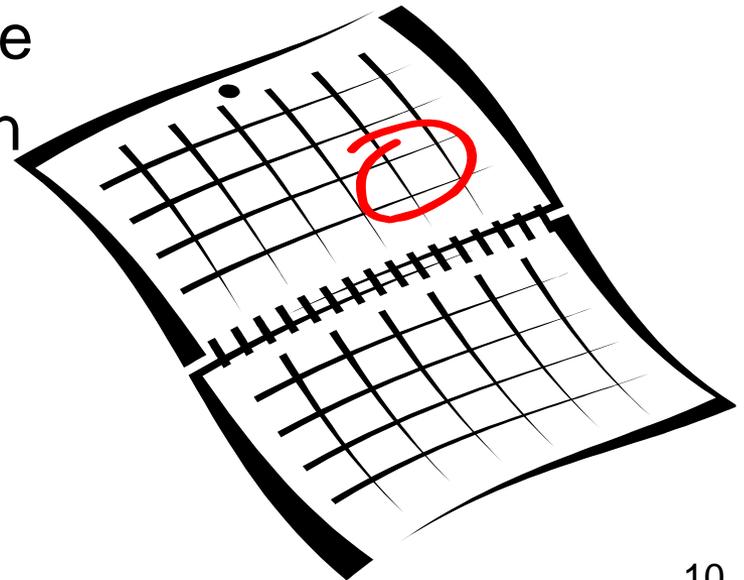


MDCH CON Org Chart



The CON Process

1. Applicant files letter of intent
2. Applicant files completed application
3. Department reviews application
4. Applicant has 15 days to submit information to DCH
5. DCH determines the review type
6. Proposed decision issued within deadlines for each review type
 - Nonsubstantive – 45 days
 - Substantive – 120 days
 - Comparative – 150 days

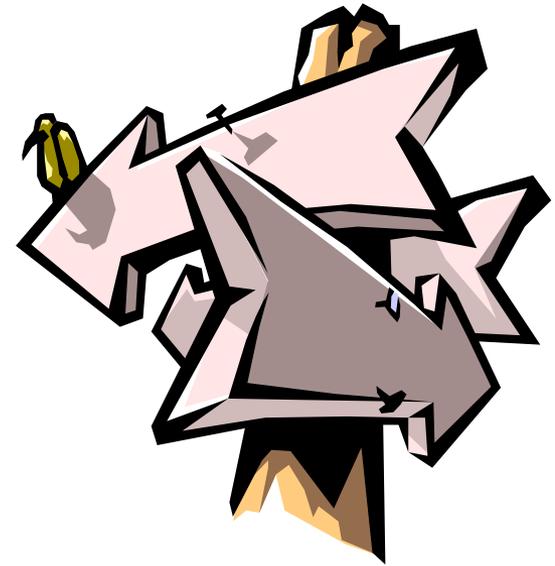


CON Process Continued...

7. Proposed decision approved

8. Proposed decision not approved

9. Hearing is not requested



10. Hearing is requested

11. DCH Director makes final decision



Statutory Authority for Review of Standards Attachment B

- MCL 22215(1)(m) requires that standards be reviewed, and revised if necessary, every 3 years. Statute also requires that the Commission “If determined necessary by the Commission, revise, add to, or delete 1 or more of the covered clinical services listed in section 22203....” [MCL 22215(1)(a)]



Statutory Authority for Review of Standards Continued

Attachment B

- MCL 22215(1)(n) states “If a standard advisory committee is not appointed by the commission and the commission determines it necessary, submit a request to the department to engage the services of private consultants or request the department to contract with any private organization for professional and technical assistance and advice or other services to assist the commission in carrying out its duties and functions under this part.”

Standard Advisory Committee (SAC) Responsibility

Attachment B

- Public Health Code, Act 368 of 1978
 - MCL 333.22215 “...(1)(I) If the Commission determines it necessary, appoint standard advisory committees to assist in the development of proposed certificate of need review standards. A standard advisory committee shall complete its duties under this subdivision and submit its recommendations to the Commission within 6 months unless a shorter period of time is specified by the Commission when the standard advisory committee is appointed....”

Development of the Charge

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

**CARDIAC CATHETERIZATION SERVICES
STANDARD ADVISORY COMMITTEE (SAC) CHARGE**

**Approved by the CON Commission Chairperson as Delegated by the CON Commission on
January 28, 2014**

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

1. Determine if elective therapeutic cardiac catheterizations should be allowed at facilities that do not provide on-site open heart surgery services by considering the recommendations of national organizations. If it is recommended that these services should be allowed:
 - a. consider the impacts of cost, quality and access under the current standards in determining need for this service; and
 - b. provide specific criteria for this service including initiation and maintenance volumes as well as patient safety and quality criteria.
2. Develop language for a second acquisition, similar to that of other standards.
3. Develop specific measurable quality metrics in the project delivery requirements, similar to that of Open Heart Surgery (OHS) standards.
4. Consider any technical or other changes from the Department, e.g., updates or modifications consistent with other CON review standards and the Public Health Code.

SAC Operations

- Operates using modified Roberts' Rules
- Subject to Open Meeting Act; including public comment period which is placed on the agenda
- The Chair or a designee (SAC member) appointed by the Chair can run the meeting
- A physical quorum is necessary to conduct business
- Although SAC members may participate by phone; phone participation is not included in the quorum count or a vote
- A quorum is defined as a majority of the members appointed and serving
- If a quorum of the SAC members is present at any gathering, this becomes a public meeting
- Final recommendations are made by the SAC to the CON Commission. The SAC presents a written report and/or final draft language.

CON Commission Action

- Commission receives final report of the SAC
- Determines what proposed action will be taken based upon SAC recommendations



Legislative Oversight of Proposed Changes to CON Standards

- Any potential changes to existing standards are required to be reviewed by the Joint Legislative Committee (JLC)
- The JLC includes the chairs of the health policy committees from both the Senate and the House of Representatives
- After the CON Commission has take proposed action and no less than 30 days prior to the Commission taking final action, a Public Hearing is conducted by the Commission
- Notice of the proposed action, along with a brief summary of the impact of any changes, is provided and sent to the JLC for its review

.....Legislative Oversight Continued

- Upon the Commission taking final action, the JLC and the Governor are provided notice of the proposed final action as well as a brief summary of the impact of any changes that have been proposed by the CON Commission
- The JLC and Governor have a 45-day review period to disapprove the proposed final action. Such 45-day review period shall commence on a legislative session day and must include 9 legislative session days
- If the proposed final action is not disapproved, then it becomes effective upon the expiration of the 45-day review period or on a later date specified in the proposed final action

Cardiac Cath Standard Advisory Committee

Overview of Data
Tulika Bhattacharya
CON Evaluation Section

Cardiac Cath Services

- ▶ "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or physiological problems in the heart. Procedures include PCI, PTCA, atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD device implantations, transcatheter valve, other structural heart disease procedures, percutaneous transluminal coronary angioplasty (PTCA) and coronary stent implantation and left sided arrhythmia therapeutic procedures. The term does not include the intra coronary administration of drugs where that is the only therapeutic intervention.
- ▶ "Diagnostic cardiac catheterization service" means providing diagnostic cardiac catheterization procedures on an organized, regular basis in a laboratory to diagnose anatomical and/or physiological problems in the heart. Procedures include the intra coronary administration of drugs; left heart catheterization; right heart catheterization; coronary angiography; diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic). A hospital that provides diagnostic cardiac catheterization services may also perform implantations of cardiac permanent pacemakers and ICD devices.
- ▶ "Primary percutaneous coronary intervention (PCI)" means a PCI performed on an acute myocardial infarction (AMI) patient with confirmed ST elevation or new left bundle branch block.

Open Heart Surgery Service

- ▶ "Open heart surgery" means any cardiac surgical procedure involving the heart and/or thoracic great vessels (excluding organ transplantation) that is intended to correct congenital and acquired cardiac and coronary artery disease and/or great vessels and often uses a heart–lung pump (pumps and oxygenates the blood) or its equivalent to perform the functions of circulation during surgery. These procedures may be performed off–pump (beating heart), although a heart–lung pump is still available during the procedure.
- ▶ "Open heart surgical case" means a single visit to an operating room during which one or more OHS procedures are performed.

** An applicant proposing to initiate either adult or pediatric OHS as a new service shall be a hospital and operating or approved to operate a diagnostic and therapeutic adult or pediatric cardiac catheterization service, respectively.

CC, OHS & Primary PCI (CY2013)

- ▶ 62 hospitals provide cardiac cath (CC) services
- ▶ 33 hospitals provide adult OHS & therapeutic CC service (of which 2 provides pediatric OHS/therapeutic CC also)
- ▶ 1 hospital provide pediatric OHS & therapeutic CC service
- ▶ 14 hospitals provide Primary PCI w/o on-site OHS backup
- ▶ 15 hospitals provide diagnostic only CC service

CON Survey Data

	Diagnostic CC	Therapeutic CC	Complex Valvular	OHS	Primary PCI
2013	88,489	70,962	795	11,412	709
2012	91,691	68,371	1033	11,437	738
2011	105,760	65,639	1164	11,814	691*

* 3 facilities not operational in 2011

CARDIAC CATHETERIZATION SERVICES

STANDARD ADVISORY COMMITTEE (SAC) CHARGE

Approved by the CON Commission Chairperson as Delegated by the CON Commission on January 28, 2014

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

1. Determine if elective therapeutic cardiac catheterizations should be allowed at facilities that do not provide on-site open heart surgery services by considering the recommendations of national organizations. If it is recommended that these services should be allowed:
 - a. consider the impacts of cost, quality and access under the current standards in determining need for this service; and
 - b. provide specific criteria for this service including initiation and maintenance volumes as well as patient safety and quality criteria.
2. Develop language for a second acquisition, similar to that of other standards.
3. Develop specific measurable quality metrics in the project delivery requirements, similar to that of Open Heart Surgery (OHS) standards.
4. Consider any technical or other changes from the Department, e.g., updates or modifications consistent with other CON review standards and the Public Health Code.