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

Wednesday November 10, 2010

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 @ 9:34 a.m.

A. Members Present:

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

B. Members Absent:

Robert Goodman, MD, MHSA, FACEP, Blue Cross Blue Shield/Blue Care Network

C. Michigan Department of Community Health Staff present:
Irma Lopez
Natalie Kellogg
Tania Rodriguez
Jessica Austin
Brenda Rogers
Sallie Flanders
William J Hart
Linda Collins

II. Introduction of Members & Staff

III. Declaration of Conflicts of Interests

No conflicts were declared.

IV. Review of Agenda

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

V. Basic CON Review

The Department gave a brief review of the CON Process (see Attachment A) Discussion Followed.

VI. Review & Discussion of Charge

Chairperson Eagle gave a brief review of each of the 8 points of the Charge (see Attachment B)

Public Comment:
Dennis McCafferty - Economic Alliance for Michigan

A. First Point:

Dr. Sotille volunteered to work with the Department on gathering other state information regarding CON regulation and costs. He will provide the Committee with a map of hospitals with Cardiac Catheterization Labs vs. hospitals without.

Ashkar recommended and later volunteered to collaborate with the Department on current trend information in regard to other state's methodologies for regulation vs. deregulation

Dr. Schrieber volunteered to review ACC (American College of Cardiology) guidelines

Public Comment:
Dennis McCafferty- Economic Alliance for Michigan

Dr. Sotille volunteered to explore costs by reviewing Michigan Hospital Association and Blue Cross Blue Shield reports and data.

Dr. Riba will provide a simulation study differentiating between therapeutic and diagnostic expansion of PCI in hospitals with no surgical back up vs. those that include surgical back up.

B. Second Point:

Chairperson Eagle recommended presentation regarding preventative/interventional care at the state and national level. Specifically how many states allow and if so what restrictions are associated?

Dr. Dobies recommended looking at organized primary PCI procedures with Cardiac Catheterization Labs, specifically, the European models.

C. Third Point:

Dr. Lewis volunteered to provide further information on non-invasive preventive care.

D. Fourth Point:

No Discussion

E. Fifth Point:

Dr. Pielsticker and out of state doctor(s) will provide further information on state guidelines for Primary PCI. Additionally, the Department will be exploring what information the Department can gather.

F. Sixth Point:

Dr. Schreiber volunteered to obtain information regarding anticipated changes to percutaneous valve intervention.

Dr. Dobies volunteered to provide further information on current minimum volume requirements and to review the CON standards.

G. Seventh Point:

The Department clarified CON requirements for replacement vs. upgrade and advised that the Department will look at this and make its recommendations.
Dr. Weaver advised he would also like to review the CON requirements.
Dr. Dudar and Dr. Schreiber responded that they will review volume issues and requirements.

H. Eighth Point:

The Department clarified Point 8 is to be handled by the Department and staff will recommend necessary technical changes.

VII. Public Comment:

Dennis McCafferty- Economic Alliance for Michigan

VIII. Next Steps and Future Agenda Items

The Department advised the SAC that all information for the next meeting will need to be submitted to the Department by 11/22/2010 for timely posting and mailing.

Chairperson Eagle advised that he will create an agenda based on the information gathered.

IX. Future Meeting Dates:

A. December 1, 2010
B. January 6, 2011
C. February 8, 2011
D. March 10, 2011
E. April 6, 2011
F. May 4, 2011

X. Adjournment

Motion by Donovan and seconded by Wells to adjourn the meeting @ 11:09 a.m. Motion Carried.

Basics of Certificate of Need (CON)
CC SAC
November 10, 2010

Certificate of Need Federal Background

- 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 A

- 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.

MDCH

Michigan CON Background

- 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?

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

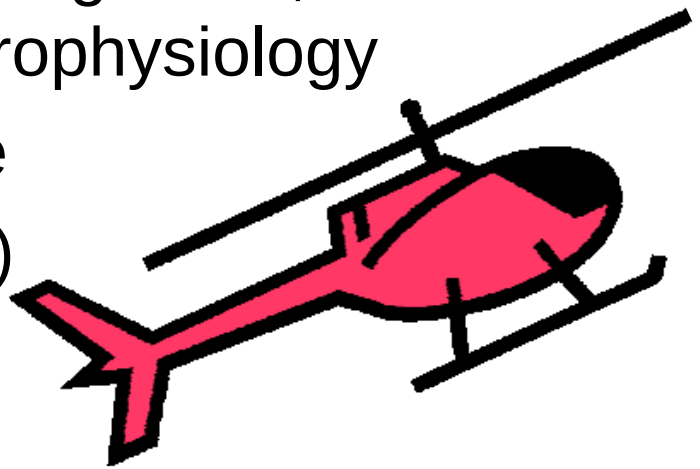
Capital expenditure projects (i.e., construction, renovation) must obtain a CON if the projects meet the following threshold:

- $2,942,500 for clinical service areas (January 2010)

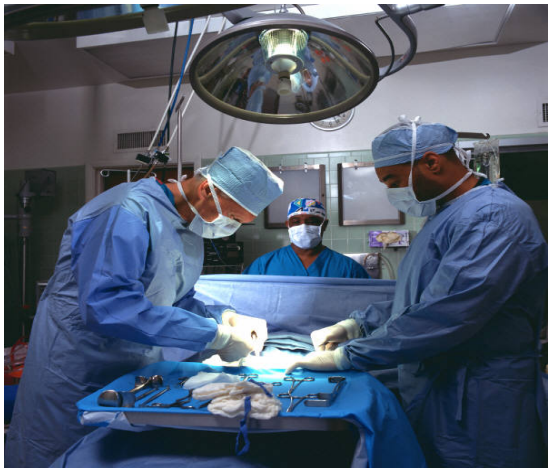
Note: Threshold is indexed annually by the Department based on the Consumer Price Index.

Categories That Require CON Approval

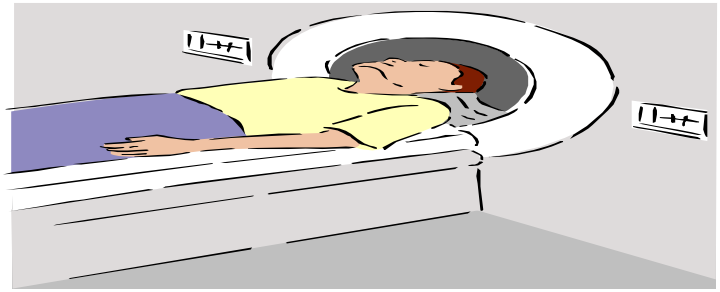
- Air ambulances (helicopters)
- Cardiac catheterization, including diagnostic, therapeutic, angioplasty, and electrophysiology
- Hospital beds – general acute care
- Magnetic resonance imaging (MRI)
- Megavoltage radiation therapy
- Neonatal intensive care units
- Nursing home/hospital long-term care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



Categories That Require CON Approval



- 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, liver, and pancreas
- Computed tomography (CT) scanners



MDCH CON Org Chart

Attachment A

Janet Olszewski, Director

Kurt Krause, Chief Deputy Director

Nick Lyon, Deputy Director, Health Policy,
Health Policy and Regulation Administration

Vacant
Bureau of Legal & Policy Affairs

Stan Nash

Bill Hart, Director, Bureau of
Health Policy & Access Division

Linda Collins, Secretary

Health Policy Section and Commission Support

Irma Lopez, Manager

Jessica Austin

Natalie Kellogg

Brenda Rogers

Tania Rodriguez

Karen McCosky

Access to Care Section

Lonnie Barnett, Manager

Andy Chen

Bob Esdale

Ian Horste

Holly Mayes

Ken Miller

Amber Myers

Traci Wightman

CON Evaluation Section

Larry Horvath, Manager

Rose Moye

Sallie Flanders

Andrea Moore

Tulika Bhattacharya

Perry Smith

Joette Laseur

Matt Weaver

Gaye Tuttle

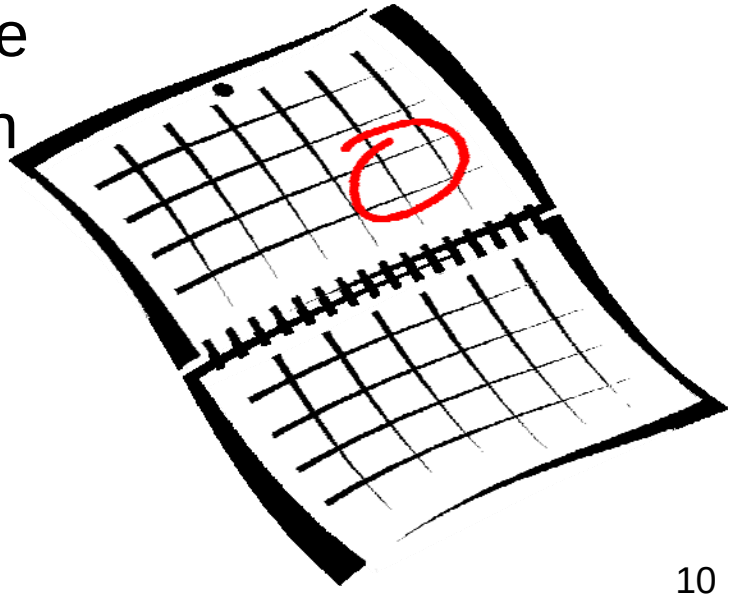
Zena Flanders

Chad Thelen

Phillip Benedict

The CON Process

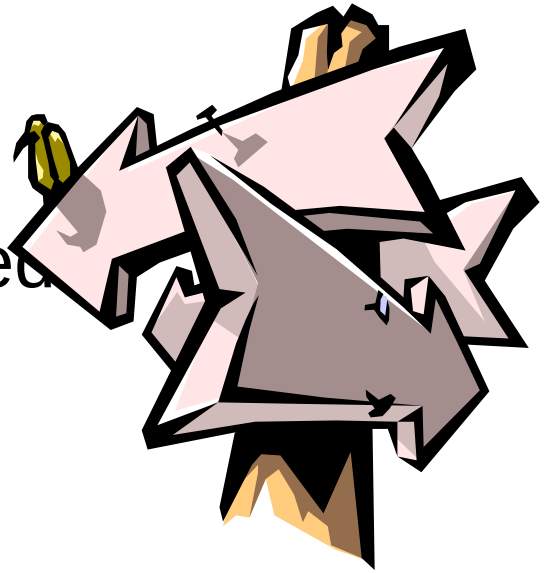
1. Applicant files letter of intent
2. Applicant files completed application
3. Department reviews application
4. Applicant has 15 days to submit information to DCH
5. DCH determines the review type
6. Proposed decision issued within deadlines for each review type
    - Nonsubstantive – 45 days
    -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

- 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

- 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

- Public Health Code, Act 368 of 1978
  - MCL 333.22215 "…(1)(*l*) 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 Hearing 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) DRAFT CHARGE
Approved by the CON Commission Chairperson and Vice-Chairperson as Delegated by the CON Commission on June 10, 2010

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. 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.

2. Determine if elective therapeutic cardiac catheterizations 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.

3. Review and update, if necessary, the methodology for determining procedure equivalents. If needed, review existing methodologies for determining need.

4. Clarify what procedures shall count toward meeting volume requirements, including minimum volume requirements, specifically for diagnostic cardiac catheterization, therapeutic cardiac catheterization, and total laboratory volume requirements.

5. Review and update, if necessary, requirements to initiate primary PCI services for patients experiencing AMI.

6. Review existing criteria, volume requirements, and procedure equivalents to determine necessary modifications, if any, related to new cardiac catheterization technology, evolving medical techniques, e.g., percutaneous insertion of cardiac valves.

7. Consider separation of replace/upgrade requirements.

8. Consider any technical or other changes from the Department or SAC, 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

Attachment A

- 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 CATHETERIZATION SERVICES

STANDARD ADVISORY COMMITTEE (SAC) DRAFT CHARGE

Approved by the CON Commission Chairperson and Vice-Chairperson as Delegated by the CON Commission on June 10, 2010

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. 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.

2. Determine if elective therapeutic cardiac catheterizations 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.

3. Review and update, if necessary, the methodology for determining procedure equivalents. If needed, review existing methodologies for determining need.

4. Clarify what procedures shall count toward meeting volume requirements, including minimum volume requirements, specifically for diagnostic cardiac catheterization, therapeutic cardiac catheterization, and total laboratory volume requirements.

5. Review and update, if necessary, requirements to initiate primary PCI services for patients experiencing AMI.

6. Review existing criteria, volume requirements, and procedure equivalents to determine necessary modifications, if any, related to new cardiac catheterization technology, evolving medical techniques, e.g., percutaneous insertion of cardiac valves.

7. Consider separation of replace/upgrade requirements.

8. Consider any technical or other changes from the Department or SAC, e.g., updates or modifications consistent with other CON review standards and the Public Health Code.