MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
NEW MEDICAL TECHNOLOGY (NEWTAC) ADVISORY COMMITTEE MEETING

Tuesday, August 14, 2007

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

APPROVED MINUTES

I. Call To Order

Chairperson Marc Keshishian called the meeting to order at 1:08 p.m.

A. Members Present:

Yvonne Abdoo, PhD, RN, School of Nursing Faculty Member
Raymond Breiding, Health Care Provider Organization Representative
Thomas Cooper, School of Osteopathy Faculty Member
David Ellis, Member Knowledgeable in Medical Technology
John Fox, MD, Third Party Payer Organization Representative
Maureen Halligan, Health Care Provider Organization Representative
Marc Keshishian, MD, Chairperson, Certificate of Need (CON) Commission
Terry Keys, Health Care Provider Organization Representative
Toshiki Masaki, Purchasing Organization Representative
Gordan Morlan, Health Care Consumer Organization Representative
Suresh Mukherji, MD, School of Medicine Faculty Member
Conrad Nagle, MD, Health Care Provider Organization Representative
Manuel Valdivieso, MD, Health Care Provider Organization Representative (Arrived @ 1:15)
Don VeCassey, Health Care Consumer Organization Representative
Michael Witt, PharmD, Member Knowledgeable in Medical Technology (Arrived @ 1:12)

B. Members Absent:

Roland Palmer, Health Care Provider Organization Representative
Predrag Sukovic, PhD, Member Knowledgeable in Medical Technology

C. Michigan Department of Community Health Staff Present:

Lakshmi Amarnath
Jan Christensen
Bill Hart
John Hubinger
Irma Lopez
Andrea Moore
Taleitha Pytlowanyj
Brenda Rogers
Matt Weaver

II. Declaration of Conflicts of Interests

No conflicts were stated at this time.

III. Review of Agenda

There was a brief introduction of the members and Department staff.

Motion by Ms. Abdoo, seconded by Mr. VeCasey, to accept the agenda as presented. Motion Carried.

IV. Review of Minutes – May 14, 2007

Motion by Mr. Breiding, seconded by Ms. Abdoo, to accept the minutes as presented. Motion Carried.

V. CON Overview

Ms. Rogers provided a brief overview (Attachment A) of CON to the Committee. Discussion followed.

VI. Neurointerventional Facilities – Research Update

Chairperson Keshishian provided a brief overview of Neurointerventional Facilities and provided data (Attachment B) to the Committee members. Dr. Mukherji provided the Committee with the definition of Neurointervention. He further provided some background information regarding Neurointervention. The Committee requested that the Department provide data at the next meeting that shows what other states are doing in regards to Neurointervention. Discussion followed.

Break from 2:50 p.m. to 3:05 p.m.

VII. Review/Discussion of Pre-Market Approval (PMA) Report

Chairperson Keshishian provided a brief summary. Discussion followed.

VIII. Commission Update

Chairperson Keshishian provided a brief update. He informed the Committee that the Commission is meeting on September 18. There was brief discussion on what does vascular surgery mean.

IX. Next Steps

Chairperson Keshishian requested that the Committee start thinking about what they would like to report to the Commission at their September meeting related to neurointerventional facilities and vascular surgery. Ms. Halligan has sent Technology Assessment Compendium booklets to the Department for distribution to the committee members. An overview will be provided by Maureen at the November meeting. If available, Mr. Sukovic will give an overview of the FDA PMA process at the next meeting. Mr. Witt suggested that each member should inform the Committee of any new technology in their field of work that they know may be coming out. Discussion followed.

X. Future Meeting Dates

August 30, 2007

November 20, 2007
February 27, 2008
May 28, 2008
August 27, 2008
November 18, 2008

XI. Public Comment

Dennis McCafferty, Economic Alliance for Michigan

XII. Adjournment

Motion by Mr. Witt, seconded by Ms. Abdoo, to adjourn the meeting at 3:05 p.m. Motion Carried.

Basics of Certificate of Need (CON)
August 14, 2007

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

- 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

- 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

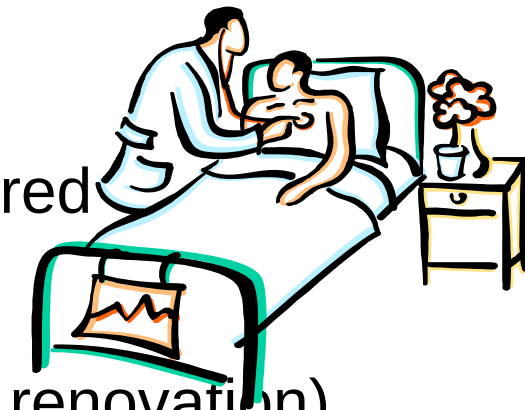
- Members appointed by Governor
  - Three year terms
  - No more than six from either political party
  - Responsible for developing and approving CON review standards w/legislative oversight

- Public Act 619 of 2002 made several modifications.
  - Expanded the Commission from 5 to 11
  - Key stakeholders are now represented on the Commission (i.e., 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



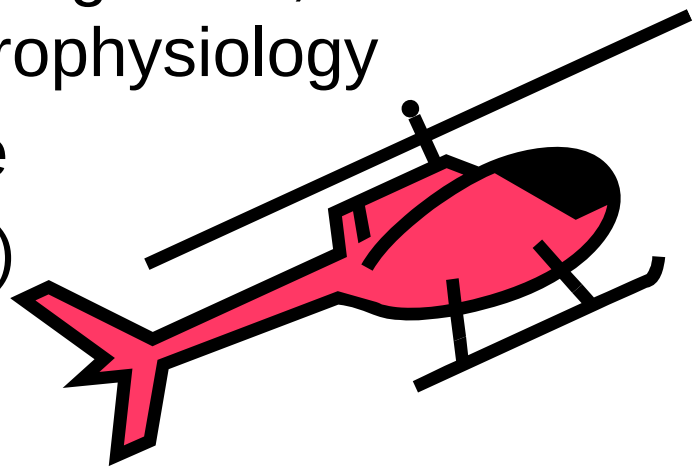
Capital expenditure projects (i.e., construction, renovation) must obtain a CON if the projects meet the following threshold:

- $2,817,500 for clinical service areas (Jan. 1, 2007)

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



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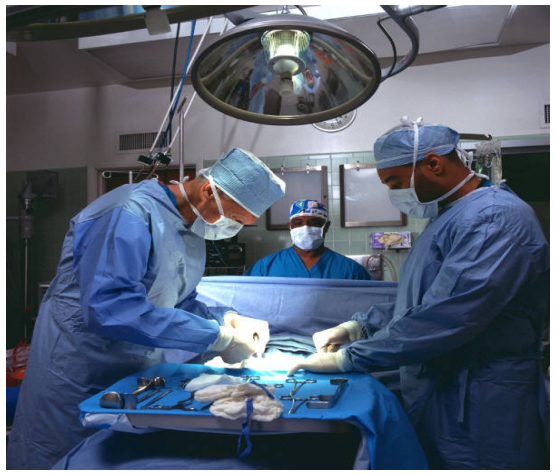


- Open heart surgery
- Positron Emission Tomography (PET)
- Psychiatric beds – acute inpatient
- Surgical services – hospital and free-standing
- Transplantation services – bone marrow, including peripheral stem cell, heart-lung, liver, and pancreas
- Computed tomography (CT) scanners

MDCH CON Org Chart

Janet Olszewski, Director

Edward Dore, Chief Deputy Director

Jan Christensen, Deputy Director, Health Policy, Regulation, & Professions Administration

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

Health Policy Section

Irma Lopez, Manager

Andrea Moore

Umbrin Ateequi

Lakshmi Amarnath

Stan Nash

Brenda Rogers

Taleitha Pytlowanyj

Karen McCosky

Phillip Benedict

Mike Dankert, Director, Bureau of Health Systems

CON Health Facilities Evaluation Section

Larry Horvath, Manager

Sallie Flanders

Carol Halsey

Tulika Bhattacharya

John Perri

Joette Laseur

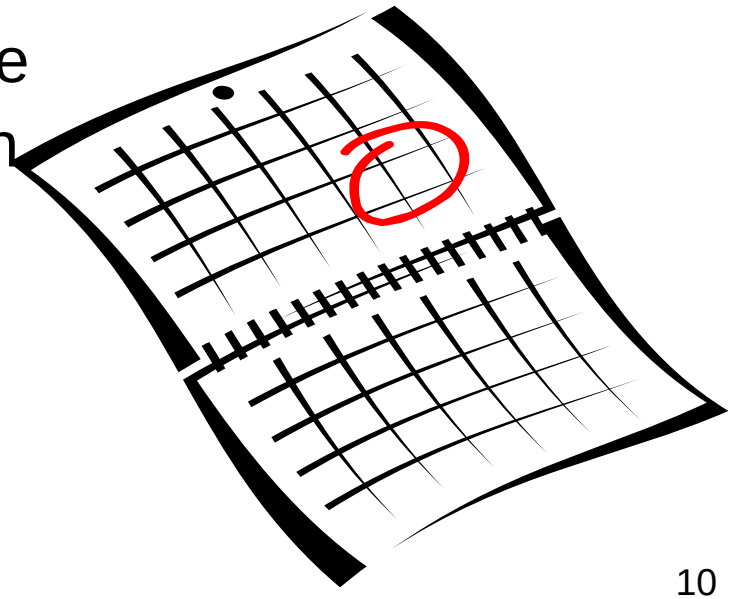
Matt Weaver

Gaye Tuttle

Zena Flanders

The CON Process

1. Applicant files letter of intent
2. Applicant files completed application form
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

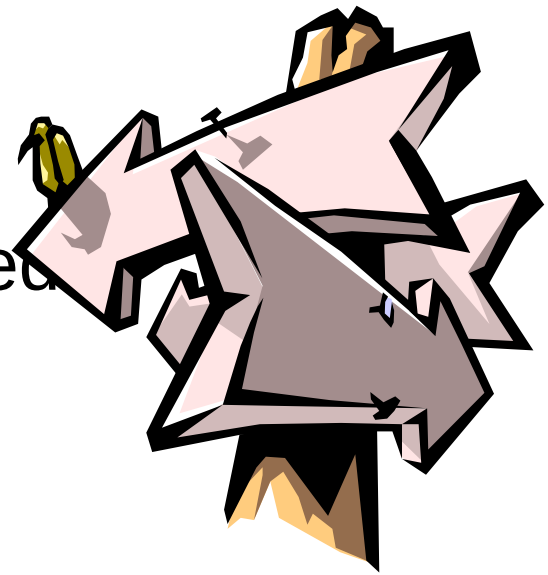


CON Process Continued…

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)]

Commission Action on New Technology

- MCL 333.22215(1)(h)
  - The CON Commission has the authority to "…Develop, approve, disapprove, or revise certificate of need review standards governing the acquisition of new technology…."

New Medical Technology Advisory Committee (NEWTAC) – Establishment & Appointments

- MCL 333.22241(3) requires that the CON Commission appoint "…a standing new medical technology advisory committee…."
- A majority of the committee "…shall be representatives of health care provider organizations concerned with licensed health facilities or licensed health professions and other persons knowledgeable in medical technology…."
- The Commission is also required to "…appoint representatives of health care consumer, purchaser, and third party payer organizations to the committee…."
- The Commission is also required to appoint faculty members from schools of medicine, osteopathy, and nursing in this state.

Role of NEWTAC

- MCL 333.22241(3)
  - "To assist in the identification of new medical technology or new medical services that may be appropriate for inclusion as a covered clinical service in the earliest possible stage of its development…."

“New Technology” Defined

- MCL 333.22241(1)
  - “…medical equipment that requires, but has not yet been granted, the approval of the federal food and drug administration for commercial use.”

New Technology Review Period

- MCL 333.22241(2)
  - "The period ending 12 months after the date of federal food and drug administration approval of new technology for commercial use shall be considered the new technology review period…."

NEWTAC Operations

- Operates using modified Roberts' Rules
- Subject to Open Meeting Act; including public comment period which is placed on the agenda
- The Chair, Vice-Chair or a designee (Committee member) appointed by the Chair can run the meeting
- A physical quorum is necessary to conduct business
- Although members may participate (and vote) by phone; phone participation is not included in the quorum count
- A quorum is defined as a majority of the members appointed and serving
- If a quorum of members is present at any gathering, this becomes a public meeting

Other CON Committees

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 on 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 January 2007
- 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

CON Commission Action

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

Legislative Oversight

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 key standing 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

….. 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 much 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

Joint Legislative Committee

- Chairperson of the Senate on Health Policy
- Vice-Chairperson of the Senate Committee on Health Policy
- Minority Vice-Chairperson of the Senate Committee on Health Policy
- Chairperson of the House of Representatives Committee on Health Policy
- Vice-Chairperson of the House of Representatives Committee on Health Policy
- Minority Vice-Chairperson of the House of Representatives Committee on Health Policy

Question Posed to CON States: Our Certificate of Need New Medical Technology Advisory Committee, a subcommittee of our Commission, is interested in knowing what other states are reviewing/regulating in regards to neurointerventional facilities/neuro radiology services and vascular surgery. Michigan currently does not regulate these services/equipment. Any insight is greatly appreciated.								
Responses Received								
Missouri	No							
New Jersey	No	Rules for Cardiac Surgery Centers & Rules for Stroke Centers						
Tennessee	No							