

**MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES
BONE MARROW TRANSPLANTATION SERVICES
STANDARD ADVISORY COMMITTEE (BMTSAC) MEETING**

Wednesday, November 8, 2015

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

APPROVED MINUTES

I. Call to Order

Chairperson Carl called the meeting to order at 9:31 a.m.

A. Members Present:

Muneer Abidi, MD, Spectrum Health Hospitals
Adil Akhtar, MD, Beaumont Hospitals
Jennifer Barish, BMT Link Network
Bruce Carl, MD, Chairperson, UAW Retiree Benefits Trust
Roland Chu, MD, Children's Hospital of Michigan
Joan Herbert, MD, MidMichigan Health
Feroze Momin, MD, Oakwood Hospital- Dearborn
Edward Peres, MD, Henry Ford Health Systems
Joseph Uberti, MD PhD, Barbara Ann Karmanos Cancer Institute
Felicia Williams, MD, BCBSM/BCN
Gregory Yanik, MD, University of Michigan Health System

B. Members Absent:

Michael Wiemann, MD, St. John Providence

C. Michigan Department of Health and Human Services Staff Present:

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

II. Introduction of Members and Staff

The SAC members and Department staff introduced themselves.

III. Declaration of Conflicts of Interests

None.

IV. Review of Agenda

Motion by Dr. Abidi, seconded by Dr. Akhtar, to accept the agenda as presented. Motion Carried.

V. Basic CON Overview

Ms. Rogers gave an overview of the CON process (see Attachment A).

VI. Review and Discussion of Charge

Chairperson Carl gave an overview of the Charge (see Attachment B).

Discussion followed.

VII. Background Material

Dr. Carl reviewed some background material (see Attachment C).

Discussion followed.

Break at 10:51 a.m. – 11:04 a.m.

VIII. Next Steps

It was noted by Chairperson Carl and requested by Dr. Akhtar to discuss Charge 4 at the December meeting before voting on Charges 1 and 2.

IX. Future Meeting Dates - December 16, 2015; January 14, 2016; February 11, 2016; March 10, 2016; April 7, 2016; May 12, 2016

X. Public Comment

None.

XI. Adjournment

Motion by Dr. Uberti, seconded by Dr. Akhtar, to adjourn the meeting at 12:03 p.m. Motion Carried.

**Basics of Certificate of Need
(CON)
Bone Marrow Transplantation
Standard Advisory Committee
(BMT SAC)
November 18, 2015**

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.

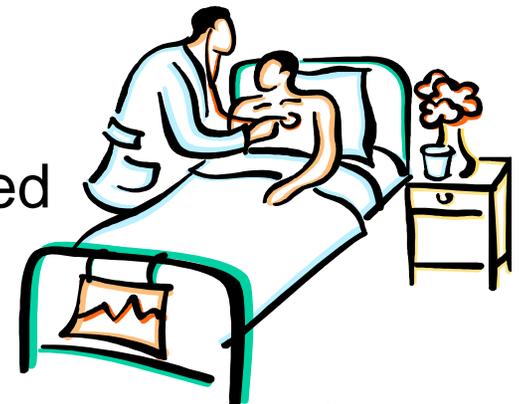
CON Commission

- 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 (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



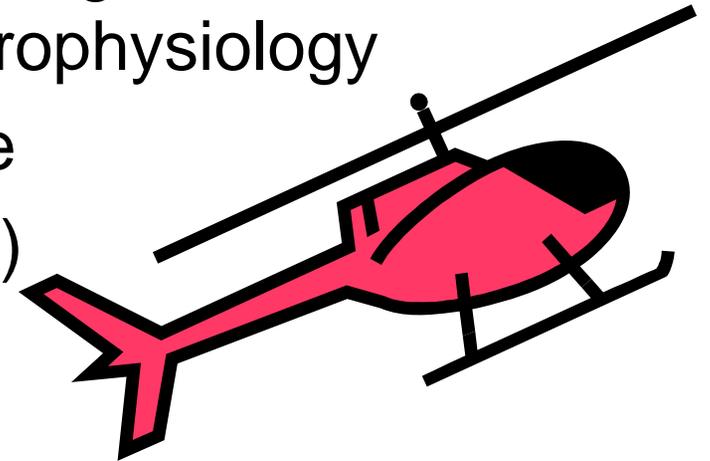
Capital expenditure projects (i.e., construction, renovation) must obtain a CON if the projects meet the following threshold:

- \$3,197,500 for clinical service areas (January 2015)

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

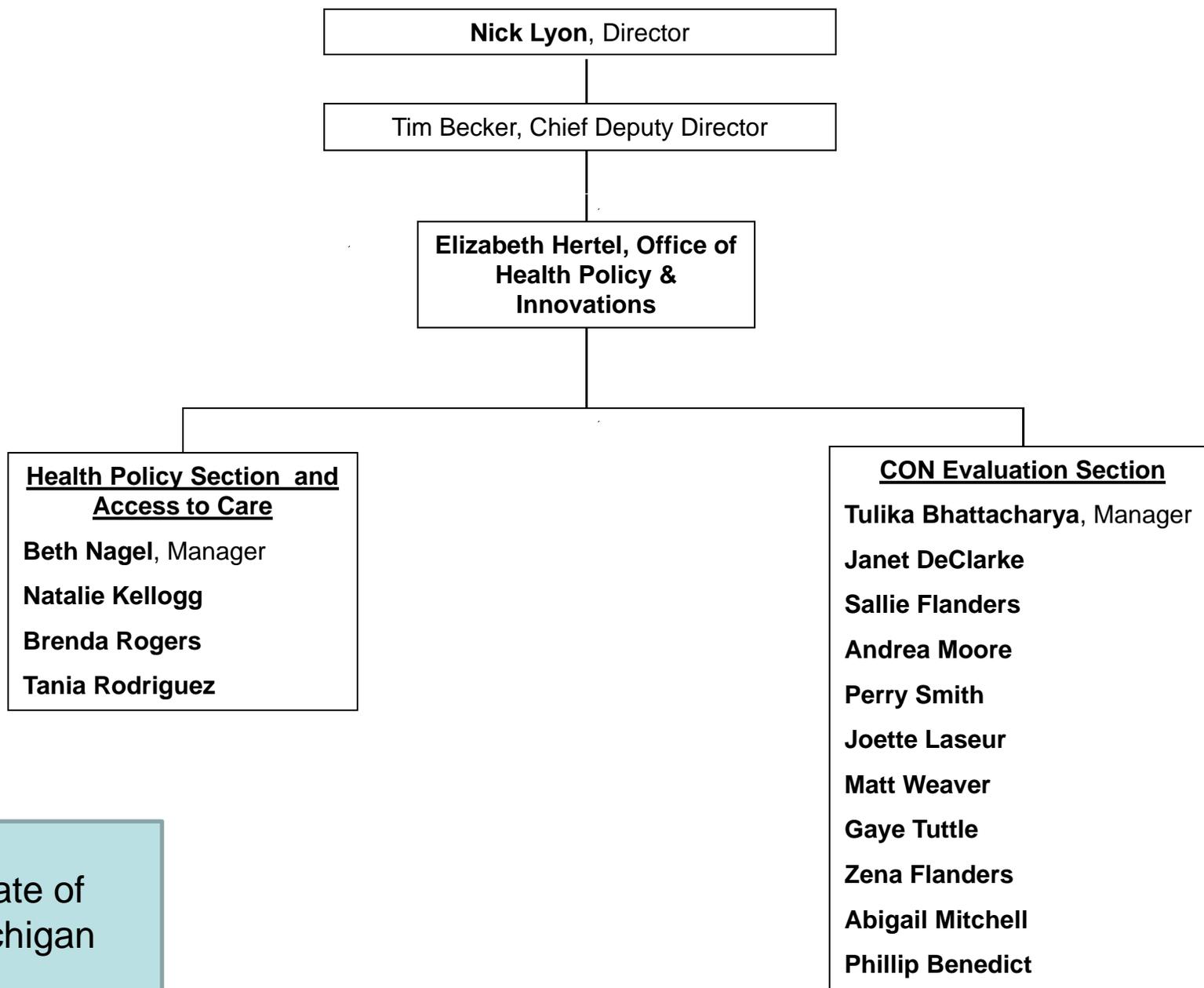


Categories That Require CON Approval

- 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

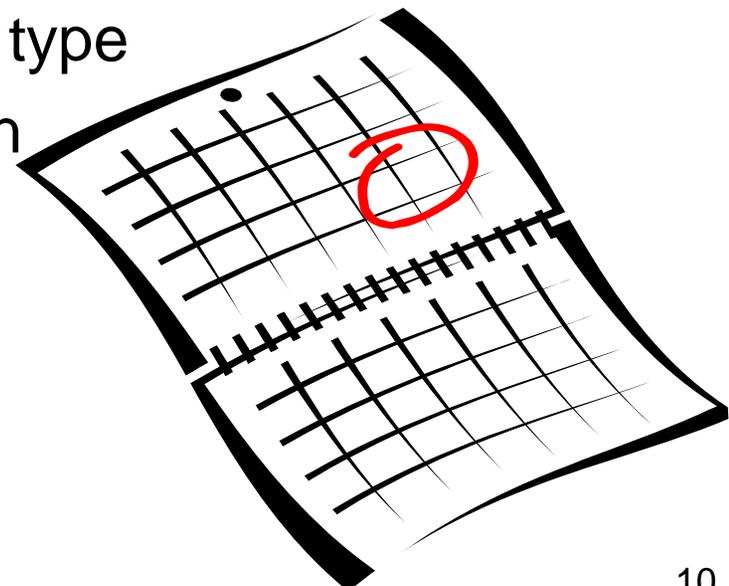


MDHHS CON Org Chart



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. MDHHS 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...

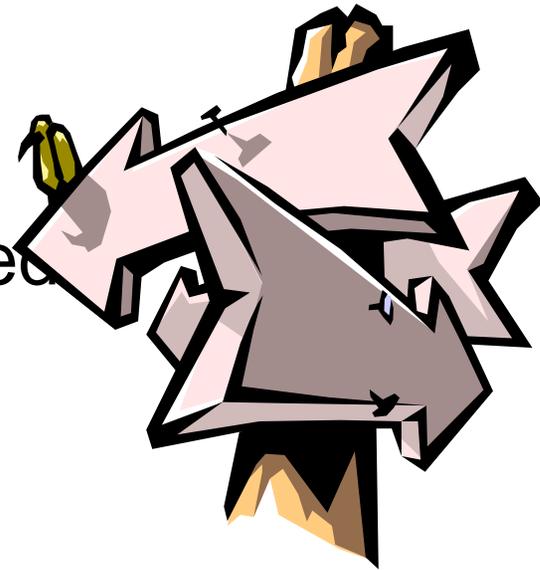
7. Proposed decision approved

8. Proposed decision not approved

9. Hearing is not requested

10. Hearing is requested

11. MDHHS 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)(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 MDHHS on behalf of the Commission
- Commission members and MDHHS staff review all of the comments/testimony received
- Recommendations offered to the Commission by the Department
- CON Commission develops and approves the final charge to the SAC

**BONE MARROW TRANSPLANTATION (BMT) SERVICES
STANDARD ADVISORY COMMITTEE (SAC) APPROVED CHARGE
Approved by the CON Commission Chairperson on June 02, 2015
as Delegated by the CON Commission on March 18, 2015**

The BMT SAC is charged to review and recommend any necessary changes to the BMT Services CON Standards regarding the following:

1. Consider and recommend if autologous BMT services should continue to be regulated by Michigan CON.
2. Consider and recommend if allogeneic BMT services should continue to be regulated by Michigan CON.
3. If the BMT SAC recommends that autologous and/or allogeneic BMT services should continue to be regulated by CON, then the SAC should recommend a methodology for determining the appropriate number of BMT services in Michigan.
4. In its deliberations of on these charges, the SAC shall consider the following: 1. National trends in CON regulation of BMT services and 2. Consistency of CON regulatory approach between BMT services and other covered clinical services.
5. Consider and report on how each recommendation address healthcare cost, quality and/or access in Michigan.
6. Consider any technical or other changes from the Department, e.g., updates or modifications consistent with other CON review standards and the Michigan 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

BONE MARROW TRANSPLANTATION (BMT) SERVICES

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FACILITY NO	TYPE	FACILITY NAME	FACILITY CITY	BMT AUTO PEDS CASES	BMT AUTO AGE 18-20 CASES	BMT AUTO ADULT CASES	BMT ALLOG PEDS CASES	BMT ALLOG AGE 18-20 CASES	BMT ALLOG ADULT CASES	BMT PARTICIPATES IN MCSP
FAC_NUM	TYPE									
410040	H	SPECTRUM HEALTH BUTTERWORTH HOSPITAL	GRAND RAPIDS	4	0	40	9	0	24	Y
810060	H	UNIVERSITY OF MICHIGAN HOSPITALS	ANN ARBOR	11	2	136	20	3	81	Y
830080	H	CHILDREN'S HOSPITAL OF MICHIGAN	DETROIT	5	0	0	17	0	0	N
830190	H	HENRY FORD HOSPITAL	DETROIT	0	0	50	0	0	27	Y
830520	H	KARMANOS CANCER CENTER	DETROIT	0	1	161	0	1	114	Y

FACILITY NO	TYPE	FACILITY NAME	FACILITY CITY	BMT ACCRED STATUS/ENTITY NAME	BMT HISTOCOMPATIBILITY LAB	TRANSPLANT PROMOTION AGREEMENT	GOOD STANDING WITH OPTN
FAC_NUM	TYPE						
410040	H	SPECTRUM HEALTH BUTTERWORTH HOSPITAL	GRAND RAPIDS	FACT	Y	Y	Y
810060	H	UNIVERSITY OF MICHIGAN HOSPITALS	ANN ARBOR	FACT	Y	Y	Y
830080	H	CHILDREN'S HOSPITAL OF MICHIGAN	DETROIT	FACT	Y	Y	Y
830190	H	HENRY FORD HOSPITAL	DETROIT	FACT	Y	Y	Y
830520	H	KARMANOS CANCER CENTER	DETROIT	FACT	Y	Y	Y