

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

Thursday, February 14, 2019

South Grand Building
333 S. Grand Ave,
1st Floor, Grand Conference Room
Lansing, MI 48933

DRAFT MINUTES

I. Call to Order

Co-Chairpersons Stella and Uberti called the meeting to order at 9:30 a.m. and asked members and staff to introduce themselves.

A. Members Present:

Philip J Stella, MD, Co-Chairperson – Trinity Health – Michigan
Joseph Uberti, MD, Co-Chairperson – McLaren Health Care
Tricia Baird, MD FAAFP MBA – Priority Health
Synnomon Harrell – International Union, UAW
Ishmael A. Jaiyesimi, MS, DO, FACP – Beaumont Hospital – Royal Oak
Daniel Lebovic, MD – Ascension Michigan
Edward M. Peres, MD – Henry Ford Health System
Natalie Pirkola – Ford Motor Company
Gordan Srkalovic, MD, PhD, FACP – Sparrow Health System (arrived at 9:40am)
Burton Vanderlaan MD – BCBSM
Stephanie Williams, MD – Spectrum Health Systems
Gregory A. Yanik, MD, BS – University of Michigan Health System

B. Members Absent:

None.

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

Tulika Bhattacharya
Marcus Connolly
Beth Nagel
Tania Rodriguez

Brenda Rogers

II. Introduction of Members and Staff

Members and staff introduced themselves.

III. Declaration of Conflicts of Interests

No conflicts were declared.

IV. Review of Agenda

Motion by Dr. Yanik, seconded by Dr. Lebovic to accept the agenda as presented. Motion carried.

V. Basic CON Overview

Brenda Rogers provided an overview of the Michigan Certificate of Need Program. (Attachment A)

VI. Review and Discussion of the Charge

Co-Chairperson Stella reviewed the charge assigned to the SAC.

Discussion followed.

VII. Next Steps

An overview of the Foundation for the Accreditation of Cellular Therapy (FACT) accreditation requirements for immune therapies will be provided at the next meeting.

Co-Chairpersons Stella and Uberti will contact Michigan Association of Health Plans (MAHP) and American Society of Clinical Oncology (ASCO) requesting input regarding FACT acceptance. Dr. Vanderlaan will check with BCBSM.

VIII. Future Meeting Dates

March 14, 2019, April 18, 2019, May 16, 2019, June 20, 2019, and July 17, 2019.

IX. Public Comment

None.

X. Adjournment

Motion by Dr. Baird, seconded by Dr. Yanik to adjourn the meeting at 11.28 a.m. Motion carried.



Michigan Certificate of Need

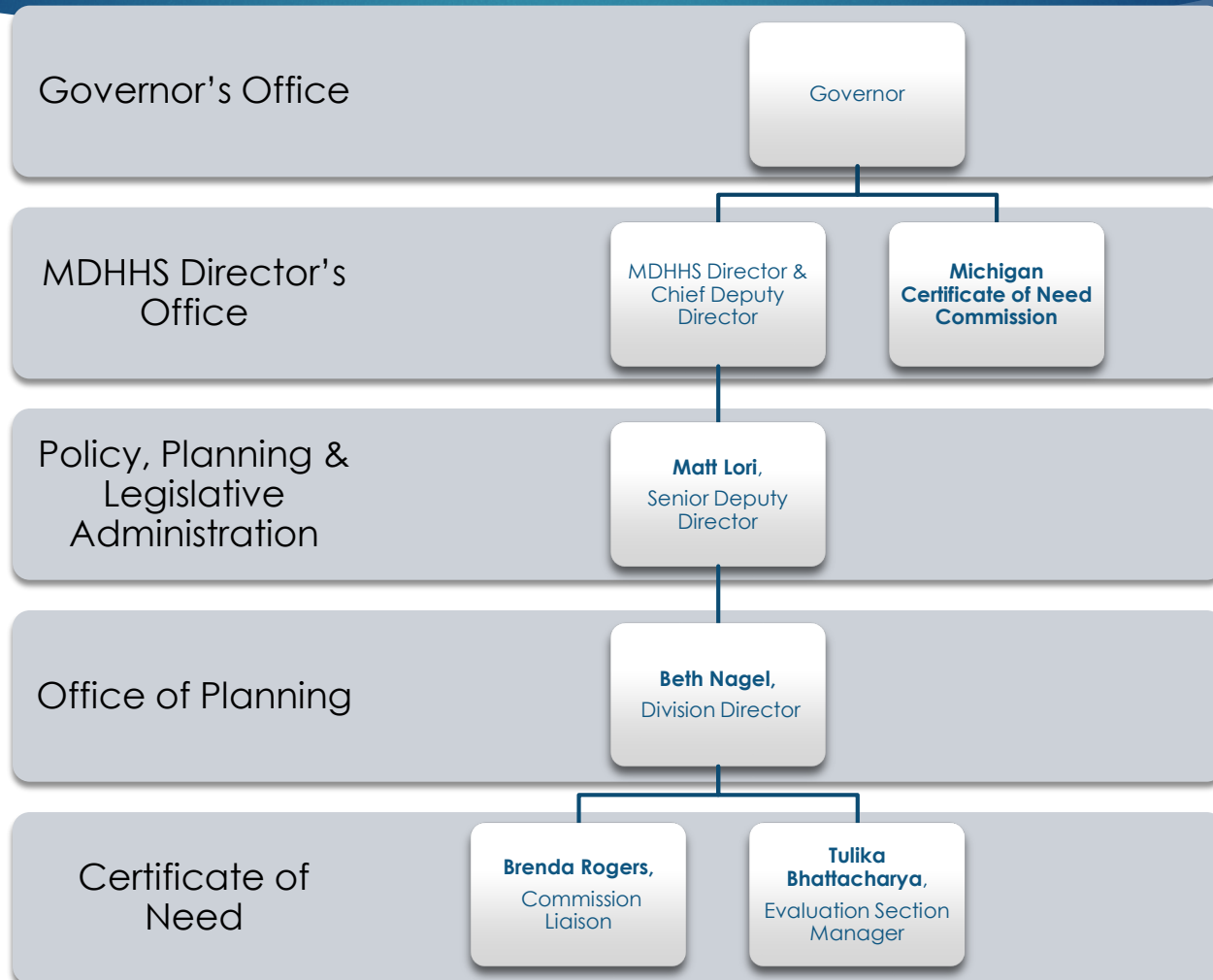
BONE MARROW TRANSPLANTATION SERVICES STANDARD
ADVISORY COMMITTEE (BMTSAC)

FEBRUARY 14, 2019

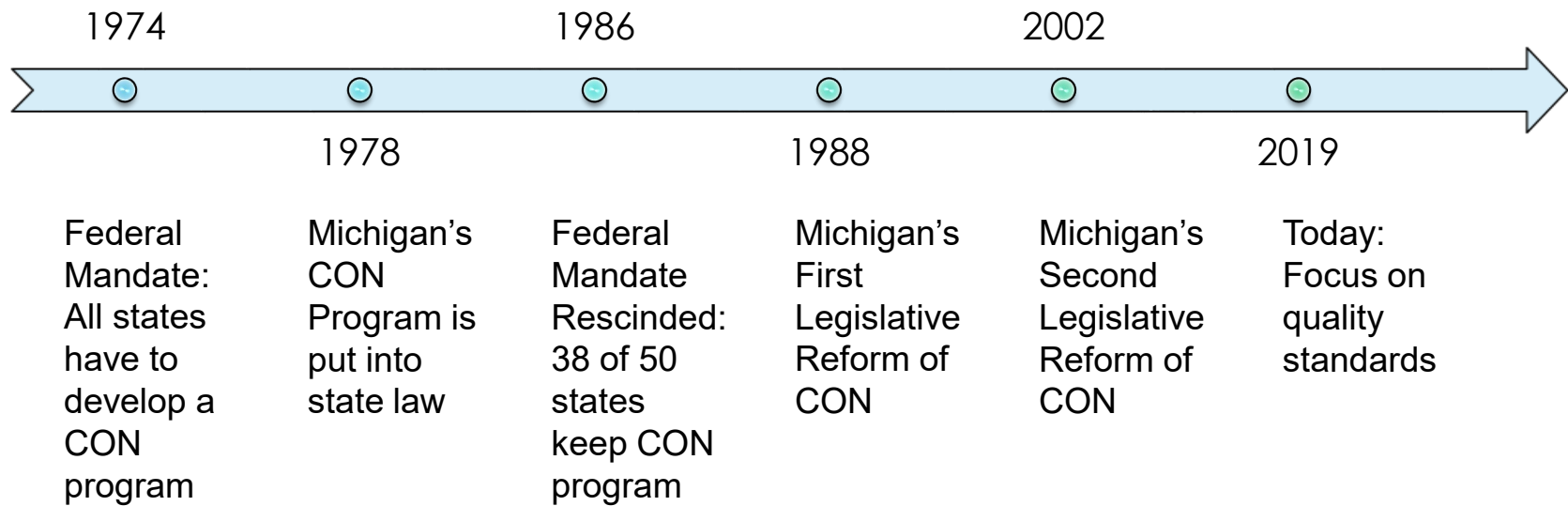
What is Certificate of Need?

- ▶ A health service & equipment regulatory program
- ▶ Created by state law
- ▶ Intended to balance cost, quality and access by ensuring that only needed health services are developed in Michigan
- ▶ Administered by the Michigan Department of Health and Human Services
- ▶ Governor-appointed Commission develops and updates standards

Organization



Michigan Certificate of Need History



What is Certificate of Need?

- ▶ A healthcare provider must apply for a Certificate of Need in order to operate one of the 15 covered clinical services

CON Covered Clinical Services

Air Ambulance Services (helicopters only)	Cardiac Catheterization Services
Computed Tomography (CT) Scanners	Hospital Beds
Magnetic Resonance Imaging (MRI)	Megavoltage Radiation Therapy (MRT)
Neonatal Intensive Care Units (NICU)	Nursing Home Beds
Open Heart Surgery Services	Positron Emission Tomography (PET) Scanners
Psychiatric Beds (Acute Inpatient)	Surgical Services
Transplant Services: Bone Marrow; Heart, Lung & Liver	Urinary Lithotripter Services

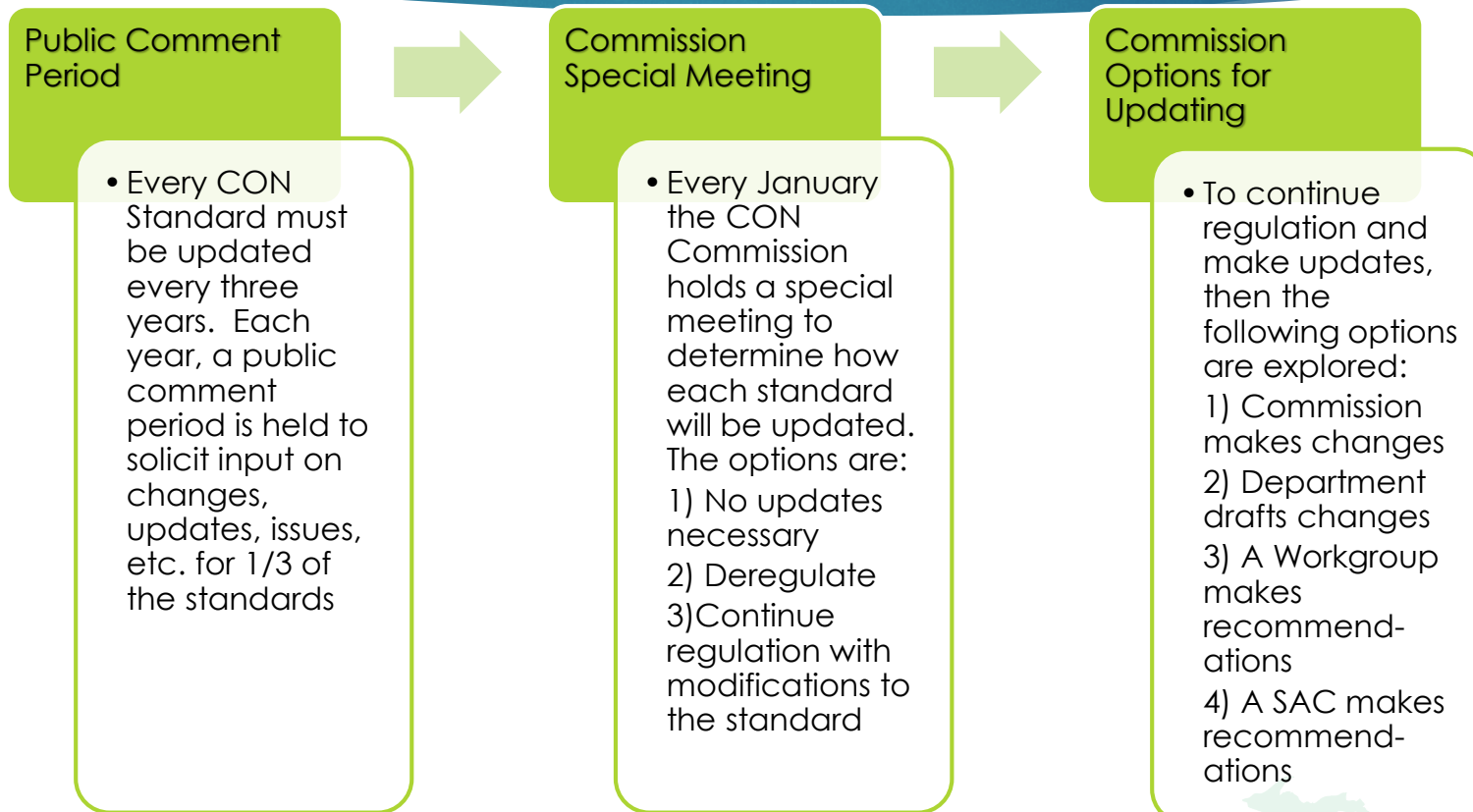
Obtaining a Certificate of Need

- ▶ In order to be approved for a Certificate of Need in Michigan, a provider must:
 - ▶ Meet Michigan CON criteria outlined in the corresponding CON standard
 - ▶ Demonstrate “need” per the corresponding CON Standard
 - ▶ Agree to specific project delivery requirements
 - ▶ Agree to meet specific service volumes
 - ▶ Provide data to MDHHS regularly for the life of the service
 - ▶ Apply for another CON before specific changes are made to the service (relocation, replacement, acquisition, for example)
 - ▶ Understand that a CON can be revoked

The Certificate of Need Standards

- ▶ Created and updated by CON Commission
- ▶ Must be updated at least every three years
- ▶ Are prospective (not retroactive)
- ▶ Contain specific requirements to initiate, replace, acquire, relocate (as necessary)
- ▶ Contain Project Delivery Requirements

CON Standard Update Process



Standard Advisory Committees

- ▶ Deliver recommendations to the CON Commission based on a specific “Charge”
- ▶ Composition outlined in statute
 - ▶ Made up of 2/3 of subject matter experts
 - ▶ Must have representatives of 1 each of consumers, providers, payers and purchasers
- ▶ Must complete work within 6 months of first meeting date
- ▶ All meetings open to the public and comply with Michigan Open Meetings Act
 - ▶ If a quorum of the SAC members is present at any gathering, this becomes a public meeting

BONE MARROW TRANSPLANTATION SERVICES
STANDARD ADVISORY COMMITTEE (BMTSAC) APPROVED CHARGE
Approved by the CON Commission Chairperson as delegated by the
Commission on March 27, 2018

The BMT SAC is charged to review if cellular therapies, such as, but not limited to, CAR-T should be considered for regulation under CON BMT services or under separate standards or if no regulation is necessary under CON at this time.

If regulation is recommended under BMT services, then review and recommend any necessary changes to the BMT Services CON Standards.

If regulation is recommended under separate standards, then make a recommendation for new standards.

Where did the Charge come from?

- ▶ 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 workgroup

Standard Advisory Committee Operations

- ▶ Operates using modified Roberts' Rules.
- ▶ The Chairperson, Co-Chairperson or a designee (SAC member if necessary) appointed by the Chair can run the meeting.
- ▶ 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.
- ▶ Final recommendations are made by the SAC to the CON Commission. The SAC Chairperson presents a written report and/or final draft language.

SAC Recommendations Process

Review Charge and make a game-plan, determine needed resources/data

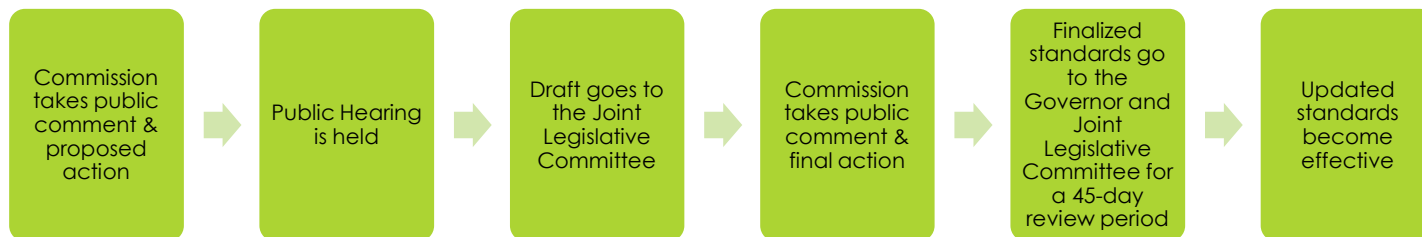
Deliberate – as a body or in sub-groups

Vote on Recommendations

End Product: Report to the Commission & Draft Language

After the SAC...

- ▶ Recommendations presented to the Commission
- ▶ Commission may:
 - ▶ Accept the Recommendations
 - ▶ Make modifications
 - ▶ Reject the Recommendations
- ▶ If changes to the Standard are to be made, then:





Search

15

- Assistance Programs
- Adult & Children's Services
- Safety & Injury Prevention
- Keeping Michigan Healthy
- Doing Business with MDHHS
- Inside MDHHS

- Doing Business with MDHHS
- Birth, Death, Marriage and Divorce Records
- Boards and Commissions
- Bridge Card Participation
- Child & Adult Provider Payments
- Child Care Fund
- Child Welfare
- Contractor Resources
- Community & Faith-Based Programs
- Forms & Applications
- MI Bridges Partners
- Health Care Providers
- Certificate of Need
- Civil Monetary Penalty (CMP) Grant Program
- Community Mental Health Services
- Departmental Forms
- Health Professional Shortage Area
- High Utilizers
- HIPAA
- Institutional Review Board

MDHHS / DOING BUSINESS WITH MDHHS / HEALTH CARE PROVIDERS / CERTIFICATE OF NEED

What's New

- Capital Expenditure Threshold for 2019
- Instructions for using e-Serve with Internet Explorer 10

How Do I?

Select a question, get an answer.

Online Tools

Select an Application or Tool

Find It Now

Select from the Quick Find List

Commission

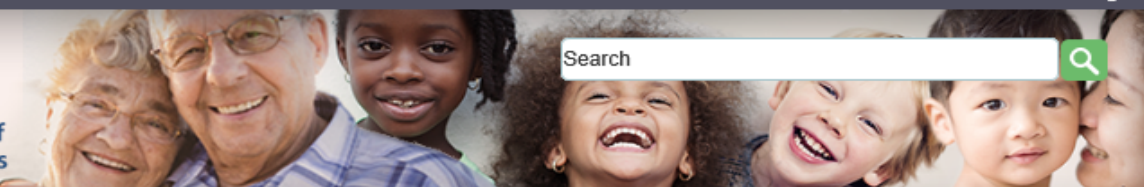
- 2019 Michigan CON Meetings
- 2019 Commission Minutes, Public Testimony, and Transcripts
- Meetings, Minutes, Public Testimony, and Audio by Calendar Year
- Commission Overview and Members
- Standard Advisory Committees (SAC)**
- Informal Workgroups
- New Medical Technology Advisory Committee (NEWTAC)
- Resource Documents

Resources

- CON Administrative Rules
- Advisories
- MAHS CON Hearing Procedures
- Part 222 of MI Public Health Code
- Part 201 of MI Public Health Code
- Review Standards

Reports

- Activity Reports
- Annual Reports
- Bed Inventories
- MRI Utilization List
- Survey Reports



Assistance Programs

Adult & Children's Services

Safety & Injury Prevention

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MDHHS / DOING BUSINESS WITH MDHHS / HEALTH CARE PROVIDERS / CERTIFICATE OF NEED

Standard Advisory Committees (SAC)

Pursuant to MCL 333.22215, a Standard Advisory Committee (SAC) may be appointed by to the Certificate of Need (CON) Commission. The purpose of the SAC is to advise the Commission regarding development of proposed CON [Review Standards](#).

The committees are composed of a two-thirds majority of experts in the subject matter, representatives of health care provider organizations concerned with licensed health facilities or licensed health professions, and representatives of organizations concerned with health care consumers, and the purchasers and payers of health care services. An individual cannot serve on more than two SACs in any two-year period and cannot be a registered lobbyist under 1978 PA 472, MCL 4.411 to 4.431.

All SAC meetings are posted on the [Meetings Page](#) and are open to the public.

Megavoltage Radiation Therapy SAC 2018
[Charge](#)
[Membership Roster](#)

Meeting Dates:

- June 28, 2018 - [Agenda & Minutes](#)
- July 26, 2018 - [Agenda & Minutes](#)
- August 30, 2018 - [Agenda & Minutes](#)
- October 3, 2018 - [Agenda & Minutes](#)
- November 1, 2018 - [Agenda & Minutes](#)
- ~~November 29, 2018 - Meeting Cancelled~~
- ~~December 19, 2018 - Meeting Cancelled~~

Cardiac Catheterization SAC 2017
[Charge](#)

[CCSAC Roster](#)

[Meeting Dates:](#)

Bone Marrow Transplant SAC 2019
[Charge](#)
[Nomination Form](#)
Membership Roster - TBD

Draft Meeting Dates:

- February 14, 2019
- March 14, 2019
- April 18, 2019
- May 16, 2019
- June 20, 2019
- July 17, 2019

Hospital Beds SAC 2017
[Charge](#)

[HBSAC Roster](#)

[Meeting Dates:](#)

July 20, 2017 - [Agenda & Minutes](#)

