MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS)
CARDIAC CATHETERIZATION SERVICES STANDARD ADVISORY COMMITTEE (CCSAC) MEETING

Thursday, August 27, 2020

Zoom Meeting

APPROVED MINUTES

I. Call to Order

Chairperson Madder called the meeting to order at 9:30 a.m.

A. Members Present:

Ryan Madder, MD, Chairperson – Spectrum Health
Kyle Sheiko, Vice-Chairperson – Michigan Outpatient Vascular Institute (MOVI)
Khaldoon Alaswad, MD, FACC, FSCAI – Henry Ford Health System (HFHS)
Omar E. Ali, MD – Detroit Medical Center (DMC)
Edouard Daher – Eastlake Cardiovascular, PC
William R. Felten, MD, MSHAL, FACC
Carlos Fernandez, DO – Edward Sparrow Hospital
Anita L. Hart, MD, FACP, SFHM – Blue Cross Blue Shield of Michigan
Srinivas Koneru, MD – K heart & Vascular Institute, PLLC
William S. Porter, RN – UAW Retiree Medical Benefits Trust
Mansoor A. Qureshi, MD – Trinity Health Michigan
Fadi A. Saab, MI – Advanced Cardiac & Vascular Centers for Amputation Prevention
Frank Saltiel, MD, FACC, FSCAI – Ascension Michigan
Steven B. H. Timmis, MD FACC – HeartPointe Cardiology (Formerly Northpointe Heart Center)
Justin Trivax, MD – Beaumont Health
Douglas J. Wunderly, MD – Bronson Healthcare Group/Advanced Cardiac Healthcare, PLC

B. Members Absent:

Susanne Mitchell – International Union, UAW

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

None.

IV. Review of Agenda

Motion by Mr. Sheiko, seconded by Mr. Daher 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

Chairperson Madder reviewed the charge assigned to the SAC and outlined a possible way of moving forward.

- Review Charges 1 – 3 at September meeting
- Review Charges 6 – 8 at October meeting
- Form a subcommittee at the September meeting for Charges 4 and 5

Discussion followed.

SAC members should email Chairperson Madder if interested in participating on the subcommittee for Charges 4 and 5. In order to seat a balanced subcommittee, Chairperson Madder asked the SAC members to state their support or opposition to Charges 4 and 5.

VII. Next Steps

Charges 1 – 3 will be reviewed at the September meeting.

Drs. Felten and Qureshi will provide presentations for Charges 1 and 2.

Mr. Sheiko will contact Dr. Forbes to present for Charge 3.

The Department will send a link to the current standards.

Chairperson Madder asked SAC members to email names of electrophysiologists to present at the October meeting for Charges 6 – 8.

Dr. Hart will reach out to SAC members as to what data they would like to see from BMC2.

VIII. Future Meeting Dates

September 24, 2020; October 22, 2020; November 19, 2020; December 17, 2020; January 14, 2021; & February 18, 2021

Future meetings will start at 8:00 a.m., and the Department will see if the meetings can start earlier.

IX. Public Comment

None.

X. Adjournment

Motion by Dr. Saltiel, seconded by Mr. Daher to adjourn the meeting at 11:08 a.m. Motion carried.

Attachment A

Michigan Certificate of Need

CARDIAC CATHETERIZATION (CC) SERVICES STANDARD ADVISORY COMMITTEE (SAC)

AUGUST 27, 2020

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

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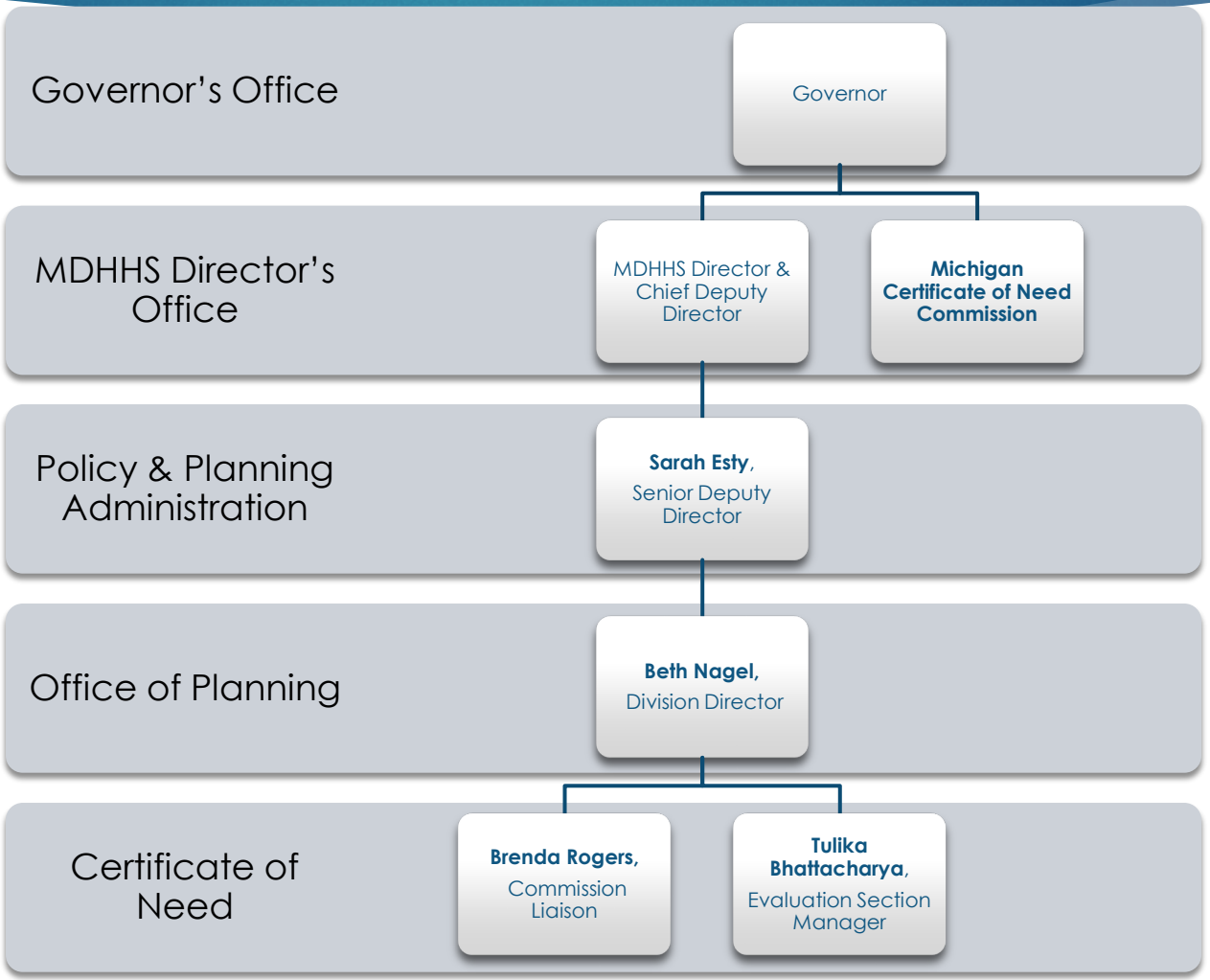
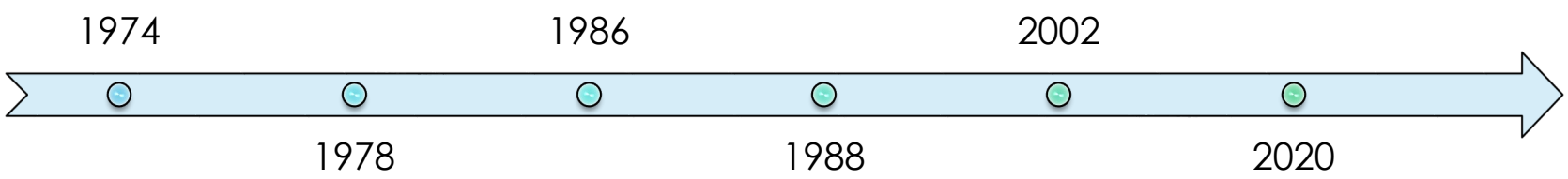
Organization



Michigan Certificate of Need History



1974	1978	1986	1988	2002	2020
Federal Mandate: All states have to develop a CON program	Michigan's CON Program is put into state law	Federal Mandate Rescinded: 38 of 50 states keep CON program	Michigan's First Legislative Reform of CON	Michigan's Second Legislative Reform of CON	Today: Focus on quality standards

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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

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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

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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

Public Comment Period

- Every CON Standard must be updated every three years. Each year, a public hearing is held to solicit input on changes, updates, issues, etc. for 1/3 of the standards

Commission Special Meeting

- Every January the CON Commission holds a special meeting to determine how each standard will be updated. The options are:

1) No updates necessary
2) Deregulate
3)Continue regulation with modifications to the standard

Commission Options for Updating

- To continue regulation and make updates, then the following options are explored:

1) Commission makes changes
2) Department drafts changes
3) A Workgroup makes recommendations
4) A SAC makes recommendations

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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 include 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

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Attachment A

CARDIAC CATHETERIZATION SERVICES
STANDARD ADVISORY COMMITTEE (SAC) APPROVED CHARGE
Approved by the CON Commission Chairperson as Delegated by the CON Commission on January 30, 2020

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

1. Review all minimum volume requirements for initiation, relocation, expansion and maintenance.

2. Review increased exceptions for more rural programs where travel would cause increased risk for the patient.

3. Review allowing patent foramen ovale (PFO) closures in facilities without open heart surgery (OHS) per the current consensus statement of SCAI/AAN.

4. Review if diagnostic cardiac catheterization services should be allowed to be performed in ambulatory surgical centers (ASCs).

5. Determine if elective PCI procedures should be allowed to be performed in ASCs.

6. Review current professional guidelines and the CON standards to evaluate the ability of elective PCI programs to perform left-sided cardiac ablations in the cases where patients have low risk Atrial Fibrillation, left-sided Premature Ventricular Contraction / Ventricular Tachycardia in the absence of severe heart failure, left sided Atrial Tachycardia, and Supraventricular Tachycardia Associated with Wolff-Parkinson-White Syndrome per the Heart Rhythm Society's (HRS) Expert Consensus Statement on Electrophysiology Laboratory Standards.

7. Review if pacemakers and implantable cardioverter defibrillator (ICD) implants should be allowed to be performed in ASCs.

CARDIAC CATHETERIZATION SERVICES
STANDARD ADVISORY COMMITTEE (SAC) APPROVED CHARGE CONTINUED

8. Determine if a hospital that provides Primary PCI without on-site OHS should be allowed to perform left-sided cardiac ablation procedures.

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

In its deliberations of the above-mentioned charges, the SAC shall consider and report on how each recommendation addresses healthcare cost, quality and/or access in Michigan.

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 SAC

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Standard Advisory Committee Operations

- Operates using modified Roberts' Rules.
- The Chair, Vice-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. (At this time, all SAC members are participating via Zoom.)
- 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 presents a written report and/or final draft language.

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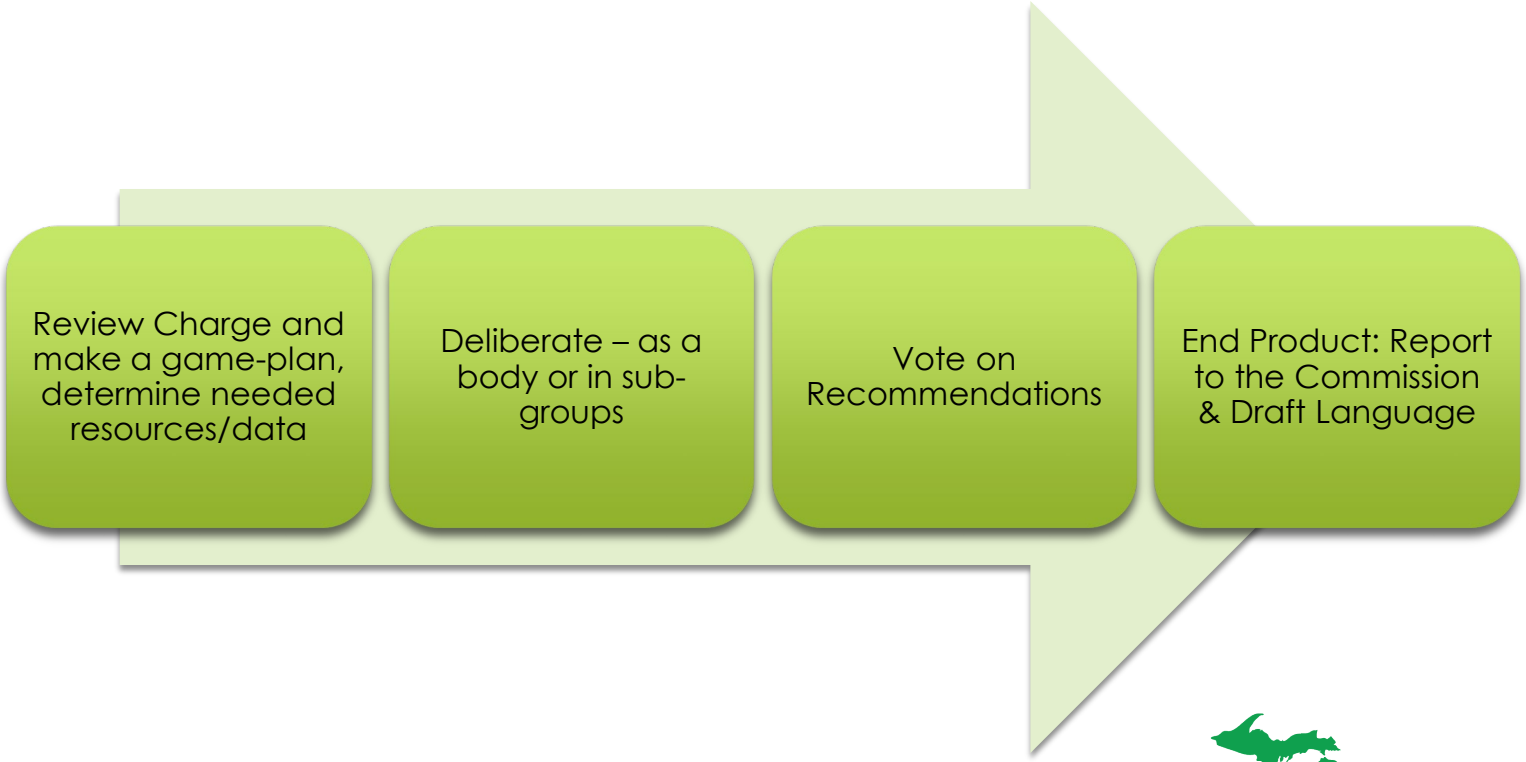
SAC Recommendations Process



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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:

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- Child Welfare
- Contractor Resources
- Community & Faith-Based Programs
- Forms & Applications
- MIBridges 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
- International Medical

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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. GO

Online Tools

Select an Application or Tool GO

Find It Now

Select from the Quick Find List GO

Commission

- 2019 Michigan CON Meetings
- 2020 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
- Administrative Hearing Rules
- Part 222 of MI Public Health Code
- Part 201 of MI Public Health Code
- Review Standards
- 2019 Brochure

Reports

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

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- Health Care Providers
- Certificate of Need

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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.

2020 SACs
Cardiac Catheterization SAC
Charge
Membership Roster
Meeting Dates:
8-27-20
9-24-20
10-22-20
11-19-20
12-17-20
1-14-21
2-18-21

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