

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH  
CERTIFICATE OF NEED (CON) COMMISSION MEETING**

Wednesday, January 26, 2011

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

**APPROVED MINUTES**

**I. Call to Order**

Chairperson Goldman called the meeting to order @ 9:36 a.m.

A. Members Present:

Edward B. Goldman, Chairperson  
James B. Falahee, Jr., JD, Vice-Chairperson  
Bradley Cory  
Charles Gayney  
Robert Hughes  
Marc Keshishian, MD  
Brian Klott  
Gay L. Landstrom, RN left @ 11:58 a.m.  
Michael A. Sandler, MD

B. Members Absent

Peter Ajluni, DO  
Michael W. Young, DO

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Community Health Staff Present:

Jessica Austin  
Melanie Brim  
William Hart Jr.  
Larry Horvath  
Natalie Kellogg  
Joette Laseur  
Tania Rodriguez  
Brenda Rogers

## **II. Review of Agenda**

Motion by Commissioner Hughes and seconded Commissioner Sandler, to add Nursing Home Bed Need as item V and approve the agenda as modified. Motion Carried.

## **III. Declaration of Conflicts of Interests**

None.

## **IV. Review of Minutes of December 15, 2010**

Motion by Vice-Chairperson Falahee, seconded by Commissioner Gayney, to approve the minutes of December 15, 2010. Motion Carried.

## **V. Nursing Home Bed Need**

A. Chairperson Goldman gave a brief overview of the Nursing Home Bed need situation.

B. Mr. Hart provided comments on the Commission's process, while Mr. Horvath provided comments on the CON application process.

Discussion Followed.

C. Public Comment:

Lody Zwareusteyn, Alliance for Health  
Bob Meeker, Spectrum Health  
Jennifer VanSkiver, Alliance for Health

Motion by Commissioner Hughes, seconded by Commissioner Landstrom, to modify the existing effective date of the Nursing Home Bed Need numbers to reflect August 1, 2011, and allow for updated calculations based on the 2010 annual census data.

Discussion Followed.

Motion by Commissioner Sandler and seconded by Commissioner Gayney, to call the question and end debate on previous motion. Motion Carried in a vote of 7- Yes, 2- No, 0-Abstain.

Vote on motion to modify the existing effective date of the Nursing Home Bed Need numbers to reflect August 1, 2011, and allow for updated calculations

based on the 2010 annual census data. Motion Failed in a vote of 1-Yes, 8-No, 0-Abstain.

D. Chairperson Goldman suggested that the next meeting agenda include discussion regarding the notification process.

**VI. Cardiac Catheterization Services - October 13, 2010 Public Hearing Summary & Report**

Mr. Hart gave a brief overview of the Departments approach for all of the standards as they are reviewed over the next 3 year period (See attachment A).

Ms. Rogers gave a brief overview of the Department's recommendations regarding Cardiac Catheterization Services (See attachment B).

A. Public Comment:

None

B. Commission Discussion

C. Commission Action:

Motion by Commissioner Sandler, seconded by Commissioner Keshishian, to accept the Department's recommendations. Motion Carried.

**VII. Hospital Bed Services - October 13, 2010 Public Hearing Summary & Report**

Ms. Rogers gave a brief overview of the Department's recommendations regarding Hospital Bed Standards, including formation of a Standard Advisory Committee (SAC) (See attachment C).

A. Public Comment:

Barbara Jackson, Blue Cross Blue Shield (See attachment D)

B. Commission Discussion

C. Commission Action

Motion by Commissioner Sandler, seconded by Commissioner Keshishian, to accept the Department's recommendations and formation of Hospital Bed SAC. Motion Carried.

Motion by Commissioner Keshishian, seconded by Commissioner Gayney, to delegate to the Chairperson and Vice-Chairperson the tasks of developing the Hospital Bed SAC charge and appointment of members to the SAC. In addition to the Department's recommendations, the charge should include review of both excess bed need and comparative review process. Motion Carried.

**VIII. Megavoltage Radiation Therapy (MRT) Services - October 13, 2010 Public Hearing Summary & Report**

Ms. Rogers gave a brief overview of the Department's recommendations regarding MRT Services (See attachment E).

A. Public Comment:

Barbra Jackson, Blue Cross Blue Shield (See attachment D)

B. Commission Discussion

C. Commission Action:

Motion by Commissioner Sandler, seconded by Commissioner Cory, to assign Departmental responsibility to collaborate with a workgroup to sort through and review MRT issues. The findings will be reported to the Commission at the March 24, 2011 meeting, where it will be decided if appointing a SAC is necessary. Motion Carried.

**IX. Open Heart Surgery Services - October 13, 2010 Public Hearing Summary & Report**

Ms. Rogers gave a brief overview of the Department's recommendations regarding Open Heart Surgery Services (See attachment F).

Break @ 11:58 a.m. - 12:14 p.m.

A. Public Comment:

Barbara Jackson, Blue Cross Blue Shield (See attachment D)  
Ken Nysson, Metro Health

B. Commission Discussion

C. Commission Action:

Motion by Commissioner Sandler, seconded by Vice-Chairperson Falahee, to assign the Department to make further recommendations based upon the outcome of the Cardiac Catheterization SAC. The

recommendations will be presented to the Commission at the June 9, 2011 meeting. Motion Carried.

**X. Positron Emission Tomography (PET) Scanner Services - October 13, 2010 Public Hearing Summary & Report**

Ms. Rogers gave a brief over view of the Departments recommendations regarding PET Scanner Services (See attachment G).

A. Public Comment:

None

B. Commission Discussion

C. Commission Action:

Motion by Commissioner Sandler, seconded by Commissioner Keshishian, to approve the Department's recommendations for PET Scanner Services and bring proposed language to the March or June Commission meeting. Motion Carried.

**XI. Surgical Services - October 13, 2010 Public Hearing Summary & Report**

Ms. Rogers gave a brief overview of the Department's recommendations regarding Surgical Services (See attachment H).

A. Public Comment:

Barbara Jackson, Blue Cross Blue Shield (See attachment D)  
Andrew Krass, Lifeline Vascular Access (See attachment I)  
Julie Green, Muskegon Surgical Center  
Jeffrey R. Schell, Saginaw Valley Neurosurgery (See attachment J)

B. Commission Discussion

C. Commission Action:

Motion by Vice-Chairperson Falahee, seconded by Commissioner Sandler, to accept the Department's recommendations and add dedicated trauma operating rooms (ORs), dedicated research ORs, vascular surgical centers, and spinal surgical centers as additional issues to be reviewed. Motion Carried.

**XII. Public Comment**

Bob Meeker, Spectrum Health

### **XIII. Review of Commission Work Plan**

Ms. Rogers gave a summary of the approved work plan (See attachment K) including the decisions made by the Commission.

A. Commission Discussion

B. Commission Action

Motion by Commissioner Sandler, seconded by Vice-Chairperson Falahee, to accept the work plan as presented with the modifications. Motion Carried.

### **XIV. Future Meeting Dates**

A. March 24, 2011

B. June 9, 2011

C. September 22, 2011

D. December 15, 2011

### **XV. Adjournment**

Motion by Commissioner Sandler, seconded by Commissioner Klott, to adjourn the meeting at 1:28 p.m. Motion Carried.

There are new voices in Michigan interested in reshaping regulations to promote a more business friendly climate. They are interested in quality requirements even if such requirements may add costs to providers.

We propose a new, focused approach across all the standards over the next three year review cycle. The Department proposes to review all standards for uniformity, streamlined methodologies, and simplified project delivery requirements.

1) Review standards for uniformity. For example, imaging standards (PET, MRI, CT) should be compared to assure uniformity between the imaging modalities. Things like replace and upgrade concepts should be similar between these standards unless there is truly an identified distinction why one service will be treated different than the others. MRI has different replace and upgrade requirements than CT and PET. These differences should be looked at as they bring confusion to the provider community. Certain things can be done in CT that are not allowed in MRI, but there is no real basis for the difference other than a different SAC recommended the language. This also holds true for beds (hospital, nursing home, psych). While there will always be some difference, we need to be sure that there are justifiable reasons for the differences. Otherwise the provider community becomes confused on why one can do one thing in one imaging standard and not in another.

2) Simplify methodologies. Many of our methodologies are very labor intensive and only have value to CON. Methodologies should not be complex or labor intensive for the provider or department. Methodologies should be based on data already collected by providers to reduce costs. Many of our current methodologies require providers to collect very finite data that only has real value to the CON methodology created. For example, the PET methodology requires existing providers to collect detailed information on every scan provided by individual patient because they must identify patient specific bed positions, number of tracers, etc. This means a PET provider needs to collect thousands of lines of code to calculate the proper weight. The data we collect should have a dual purpose: to determine compliance with the standards for pending applications as well as approved CON, and to tell us something about the health care system.

3) Streamline project delivery requirements. Project delivery requirements are the terms and condition of approval. These requirements should be reduced to not be overly burdensome to the provider community, but specific enough to help improve quality and access. Delivery requirements should not duplicate already existing and widely accepted medical practices or other licensing requirements. These requirements should be unique to CON. For example, many standards have numerous delivery requirements that are either

ambiguous, impossible to measure, or have little value. These should be removed. Remaining measures should be unique and widely agreed upon to improve the quality and outcomes of the covered service as well as improving access to the covered service. If fewer in number, we can do a better job in monitoring compliance and enforcing these requirements.

The three concepts above would move the CON program closer to a more streamlined regulatory process that is not overly burdensome to the provider community but has actual costs savings as well as measurable deliverables in health care data, quality and access.



## MDCH Recommendations for CON Standards Scheduled for 2011 Review

<b>Cardiac Catheterization Services</b> (Please refer to the attached MDCH staff analysis for additional details.)		
Should the covered service continue to be regulated?	Yes.	Continue regulation of this service as there is continued evidence that outcomes are positively impacted by volume and increase repetition.
Identified Issues	Recommended Review	Comments
Consider new percutaneous valve replacement procedures currently under FDA review.	Yes.	Consider appropriate requirements and limitations for proposed and existing hospitals approved to offer or currently offering therapeutic cardiac catheterization services.

### MDCH Staff Analysis of the Cardiac Catheterization (CC) Services Standards

#### Statutory Assignment

Pursuant to MCL 333.22215 (1)(m), the Certificate of Need (CON) Commission is to "...review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the CC Services Standards are scheduled for review in calendar year 2011.

#### Public Hearing Testimony

The Department held a Public Hearing to receive testimony regarding the Standards on October 13, 2010, with written testimony being received for an additional seven (7) days after the hearing. Testimony was received from three (3) organizations and is summarized as follows:

1. *Blue Cross Blue Shield of Michigan/ Blue Care Network*
  - Recommends that the CC standards be reviewed on a regular cycle as well as on an as needed basis; to keep the standards current and facilitate appropriate regulation of high cost and high tech medical services.
2. *Trinity Health*
  - Recommends and supports the need for continued regulation of Cardiac Catheterization Services.
3. *Economic Alliance for Michigan*
  - Provided comment and urges the Commission to consider the new valve replacement procedures utilizing catheters, rather than the current surgical process.

- Recommends evaluating the location of catheterization replacement valve procedures. Raises the question “Should these procedures only be done at high volume programs; high volume OHS or high volume therapeutic catheterization programs or both??”

### **Summary of Covered Service**

The Department received no testimony for de-regulation of Cardiac Catheterization services. Michigan is one of 26 states that regulate Cardiac Catheterization services within CON. In 2009, per the CON Annual Survey 142,138 patients had a cardiac catheterization session, within one of the 191 approved lab facilities at the 64 hospitals offering this covered service.

Currently, the Commission voted and passed a motion at the January 28, 2010 meeting to seat a Standard Advisory Committee (SAC) based on the public comment and Commission discussion. The approved charge is as follows:

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.

### **MDCH Staff Recommendations**

- **Although the CC SAC is currently underway, the Department will approach the CC SAC's leadership with an offer to work with the current SAC to review, consider, and implement, where applicable, some of the overarching principles of creating user-friendly format and language, simpler methodologies, streamlined equipment replacement requirements, and concise and value-added project delivery requirements. This is totally dependent on the CC SAC's schedule and attention to the charge they received from the CON Commission in June, 2010. The CC SAC has currently scheduled meetings monthly through May, 2011.**

**MDCH Recommendations for CON Standards Scheduled for 2011 Review**

Attachment C

<p align="center"><b>Hospital Beds Standards</b>                      (Please refer to MDCH staff summary of comments for additional detail - attached)</p>		
Should services continue to be regulated under CON?	Yes.	New hospitals and new bed towers to existing hospitals require large capital expenditures. Therefore, continued CON review is vital in assuring these large capital expenditures meet identified community need in the most cost effective way.
<b>Identified Issues</b>	<b>Recommended for Review?</b>	<b>Comments</b>
Consider review of comparative review criteria, including the use of payor mix as it accounts for 45% of the possible points.	No.	Current comparative review criteria is limited but still provides ample criteria in order for the department to determine between multiple applicants.
Conduct review of project delivery requirements.	Yes	Project delivery requirements are those requirements that a recipient of an approved CON must comply with throughout the life of the services, or unless modified by a subsequent CON approval. Review is to assure that each requirement is measurable, comports with today's standard of care, does not duplicate other regulatory requirements already established, and have cost-effective value in achieving the goals and objectives of the program to assure affordable, quality health care services for both the consumer and provider.
Conduct review of subarea methodology to determine if still applicable to today's current health care markets.		Current subarea methodology is a clustering of hospitals with similar market patterns. This methodology is not defined by geographical boundaries, often resulting in some vary large subarea crossing multiple counties and including numerous hospitals while others subareas are limited to just one hospital. Subareas are used to determine if existing hospitals can relocate beds in the same subarea and also used in determining need. A review should be conducted on the benefits and limitations of the current method as well as exploration of alternative methods.

**MDCH Staff Analysis of Hospital Bed Standards**

**Statutory Assignment**

Pursuant to MCL 333.22215 (1)(m), the Certificate of Need (CON) Commission is to "...review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the HB Services Standards are scheduled for review in calendar year 2011. Attachment C

## **Public Hearing Testimony**

The Department held a Public Hearing to receive testimony regarding the Standards on October 13, 2010, with written testimony being received for an additional seven (7) days after the hearing. Testimony was received from five (5) organizations and is summarized as follows:

1. *Steven Szelag, University of Michigan Health System (UMHS):*
  - UMHS supports the overall regulations of HB services:
  - Specifically, the high occupancy bed expansion provision that enables providers to quantitatively demonstrate need and serves as a method for relieving physical capacity constraints within a hospital.
  - UMHS would recommend that the standards not be opened for review, due to the findings based on the annual hospital survey that proves applicants who have acquired incremental bed licenses under the above provision continue to operate at an occupancy rate above the minimum threshold.
2. *Sean Gehle, The Michigan Health Ministries of Ascension Health:*
  - Ascension Health - Michigan supports the continued regulation of Hospital Beds.
  - Recommends these standards be reviewed to evaluate them in the context of CON programmatic goals of Cost, Quality, and Access.
3. *Jim Gilson, Beaumont Hospitals:*
  - Beaumont Hospital supports the overall regulations of HB services but like to recommend the following for comparative review:
  - 53%-75% of the available points in a comparative review are determined by payor mix; in addition the effect of the hospital tax more than compensates some hospitals for their higher Medicaid volumes.
  - Recommends that the comparative review criteria should also be reviewed given the health care reform and resultant impact on costs, quality, and access.
  - Further states that sources of payment or insurance should not be a CON factor.
4. *Dennis McCafferty, Economic Alliance for Michigan (EAM)*
  - Supports the formation of a SAC to review the Hospital Bed Standards
  - Recommends the SAC should add a provision in the standards that limit hospitals who are replacing existing fully-depreciated and obsolete in-patient bed capacity.
  - Recommends the number of replacement in-patient beds approved should not exceed actual average occupancy for that hospital for the prior two years, by more than 125%, this would adjust excess number of licensed capacity to actual average occupancy.

5. *Tina Weatherwax Grant, Trinity Health*

- Supports the formation of a SAC to review the Hospital Bed Standards
- Recommends enforcement or action to be taken to move the state to a more appropriately-sized number of licensed beds.
- Currently, the Department's bed inventory indicates 5,000 excess beds. Concerns for excess beds create the potential for unnecessary costs.
- Recommends revising current HB Standards language to include the release of some portion of excess beds when an applicant seeks CON review and approval of bed-related projects.

### **Summary of Covered Service**

The Department did not receive any testimony against de-regulation of Hospital Bed Standards. Michigan is one of 28 states which regulate Hospital Bed Standards within CON. In 2009, there were 174 licensed hospitals, including specialty hospitals, with 26,238 licensed acute care hospital beds. There were more than 5 million patient days of care in 2009 resulting in a statewide occupancy of 56%. On any given day more than 14,000 hospital beds are filled with an average length of stay of 4.5 days.

### **MDCH Staff Recommendations**

- **Conduct review of standards with an emphasis to assure uniformity among the various bed standards, where applicable, and create a user-friendly format.**
- **Conduct review of project delivery requirements. Project delivery requirements are those requirements that a recipient of an approved CON must comply with throughout the life of the services, or unless modified by a subsequent CON approval. Review is to assure that each requirement is measurable, comports with today's standard of care, does not duplicate other regulatory requirements already established, and have cost-effective value in achieving the goals and objectives of the program to assure affordable, quality health care services for both the consumer and provider.**
- **Conduct review of subarea methodology to determine if still applicable to today's current health care markets. Revised methodology should be based on defined geographical areas that help produce more stable population projects in the need methodology.**
- **Consider quality care requirements for applicants applying for new beds or replacing existing beds and facilities.**
- **Consider refining requirement for size of replacement hospitals.**
- **Eliminate Addendum for HIV Infected Individuals.**
- **Consider similar language from the nursing home bed standards that requires all outstanding debt obligation to the State of Michigan for Quality Assurance**

**Assessment Program (QAAP) or Civil Monetary Penalties (CMP) are paid prior to receiving or replacing hospital beds.** Attachment C

**Blue Cross  
Blue Shield**  
Of Michigan



600 E. Lafayette Blvd.  
Detroit, Michigan 48226-2998

**Testimony  
Blue Cross Blue Shield of Michigan/Blue Care Network  
MDCH Public Hearing  
October 13, 2010**

Thank you for the opportunity to provide testimony on behalf of Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network (BCN). BCBSM and BCN continue to actively support the Certificate of Need (CON) program, designed to ensure the delivery of cost-effective, high quality health care to Michigan residents.

Due to our traditional posture supporting open and transparent discussion of key issues, BCBSM and BCN support the 2011 review of scheduled CON Review Standards which include:

- o Cardiac Catheterization Services (set to be reviewed during 4th qtr 2010),
- o Hospital Beds and Addendum for HIV infected individuals
- o Megavoltage Radiations Services/Units
- o Open Heart Surgery Services
- o Positron Emission Tomography Scanner Services and Surgical Services

We feel that standards should be reviewed on a regular cycle as well as on an as needed basis. These review processes which include community input and expert consultation keep the standards current and facilitate the appropriate regulation of high cost high tech medical services.

BCBSM and BCN continue to actively support the CON program and the ongoing review of the CON Review standards in terms of cost, quality and/or access concerns. We applaud the CON Commission and MDCH staff as they continue to facilitate an objective review process, eliciting in-depth clinical expertise as well as input from consumers, purchasers, and payors. BCBSM/BCN will continue to be an open-minded, active participant in these endeavors. As always, BCBSM/BCN commends the CON Commissioners and MDCH staff for their diligent efforts in maintaining CON as a strong, vibrant program, to ensure the delivery of high quality, safe and effective health care to patients across the state.



## MDCH Recommendations for CON Standards Scheduled for 2011 Review

<b>Megavoltage Radiation Therapy (MRT)</b> (Please refer to the attached MDCH staff analysis for additional details.)		
Should the covered service continue to be regulated?	Yes	MRT services still require large initial capital investment as well as long term operating expenditures. Further, recent concerns have been raised concerning patient large-dose radiation exposure from MRT services.
Identified Issues	Recommended Review	Comments
Consider refinement to current utilization methodology for replacement and expansion of existing MRT units and services, respectively.	Yes	Current methodology is labor intensive for existing providers to accurately collect and report to the Department.
Consider modifications to Project Delivery Requirements.	Yes	Reduce number of project delivery requirements for approved services that are enforceable, objectively measurable, and achieve major objectives of assuring affordable, quality MRT services without overwhelming providers.
Consider modification to replace/upgrade definition and section.	Yes	Create distinction between replacing and upgrading an MRT unit. Simplify requirements to replace existing and outdated MRT units, while allowing upgrades without CON review/approval.

### MDCH Staff Analysis of the Megavoltage Radiation Therapy (MRT) Standards

#### **Statutory Assignment**

Pursuant to MCL 333.22215 (1)(m), the Certificate of Need (CON) Commission is to "...review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the MRT Standards are scheduled for review in calendar year 2011.

#### **Public Hearing Testimony**

The Department held a Public Hearing to receive testimony regarding the Standards on October 13, 2010, with written testimony being received for an additional seven (7) days after the hearing. Testimony was received from five (5) organizations and is summarized as follows:

1. *Walter M. Sahjidak, MD, Michigan Society of Therapeutic Radiologists & Oncologists*
  - Supports continued CON regulation.
  - Supports the formation of a Standard Advisory Committee (SAC) Workgroup.
  - Supports an update of the current review standards including the equivalent treatment visit (ETV) factoring.
  - Recommends utilizing the changes in Michigan's decreasing demographics and populations levels along with national changes in the standard of care for cancer patients as a factor in determining MRT usage in Michigan to prevent over utilization.
  
2. *Dennis McCafferty, Economic Alliance for Michigan, (EAM)*
  - Supports continued CON regulation.
  - Supports the formation of a SAC Workgroup to address strengthening the patient safety requirements related to MRT services.
  - Suggests the SAC consider strengthening the standards for additional MRT units to achieve greater proficiency, cost-effectiveness, and appropriate access.
  
3. *Tina Weatherwax Grant, Trinity Health*
  - Supports continued CON regulation.
  - Supports the formation of a SAC Workgroup to analyze and update the weights assigned to the MRT Standards.
  - Advises that the current weights used to calculate equivalent treatment visits were established nearly 5 years ago, and do not consider recent technology, techniques, and application changes to radiation therapy.
  
4. *Sean Gehle, The Michigan Health Ministries of Ascension Health*
  - Supports continued CON regulation.
  - Supports the formation of a SAC Workgroup to review the requirements for initiating a new MRT service.
  - Recommends that the language in the standards be modified to distinguish between replacement and upgrade.
  
5. *Amr Aref, MD, Radiation Oncology Specialists, PC*
  - Supports continued CON regulation.
  - Supports the formation of a SAC Workgroup to review MRT unit standards to prevent over and under utilization.
  - Supports an update of the current review standards including the equivalent treatment visit (ETV) factoring.
  
6. *Jim Gilson, Beaumont Hospitals*
  - Supports continued CON regulation.
  - Recommends the review of Section 4 and Section 12 relating to the initiation of MRT Services; specifically "relating to initiation of MRT Services: under the current standards, there is the potential for double counting of new cancer cases, which could result in overcapacity of MRT services."

## **Summary of Covered Service**

The Department did not receive any testimony against de-regulation of MRT Services Standards. Michigan is one of 25 states which regulate MRT services within CON. Per the 2009 CON Annual Survey 579,241 patients received radiation treatment in some capacity from one of 117 approved units within the 65 facilities located in the state.

## **MDCH Staff Recommendations**

- **Conduct departmental review of standards with an emphasis to assure uniformity among the various standards, where applicable, and create a user-friendly format.**
- **Conduct departmental review of project delivery requirements. Project delivery requirements are those requirements that a recipient of an approved CON must comply with throughout the life of the services, or unless modified by a subsequent CON approval. Review is to assure that each requirement is measurable, comports with today's standard of care, does not duplicate other regulatory requirements already established, and have cost-effective value in achieving the goals and objectives of the program to assure affordable, quality health care services for both the consumer and provider.**
- **Conduct departmental review to simplify projection and utilization methodologies, where possible, in a manner that is comparable to existing thresholds but reduces the labor-intensive collection process for the provider and potential applicants using readily available data.**
- **Conduct departmental review to simplify replacement requirements for existing providers to replace covered equipment in a more streamlined process that assures consumer access to advance technology and treatment services.**
- **Present proposed draft standards to Commission at the June 9, 2011 meeting.**

## MDCH Recommendations for CON Standards Scheduled for 2011 Review

<b>Open Heart Surgery (OHS)</b> (Please refer to the attached MDCH staff analysis for additional details.)		
Should the covered service continue to be regulated?	Yes.	Continue regulation of this service as there is continued evidence that outcomes are positively impacted by volume and increase repetition.
Identified Issues	Recommended Review	Comments
Review current minimum requirements for initiation and maintenance of an open heart surgical program at 300 open heart surgical cases.	Yes.	The cardiac surgery volumes are declining across the state. The initiation and maintenance volumes should be reviewed to determine appropriateness on cost, quality and access, pending the CCSAC decision.
Consider modifications to Project Delivery Requirements.	Yes.	Review project delivery requirements for approved services that are enforceable and achieve major objectives of assuring affordable, quality open heart services without overwhelming providers.
Consider refinement to current utilization methodology.	Yes.	Review current methodology to assure it accurately reflects community need for open heart services. Update methodology, if continued, with revised weights according to current standards.

### MDCH Staff Analysis of Open Heart Surgery (OHS) Standards

#### **Statutory Assignment**

Pursuant to MCL 333.22215 (1)(m), the Certificate of Need (CON) Commission is to "...review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the OHS Services Standards are scheduled for review in calendar year 2011.

#### **Public Hearing Testimony**

The Department held a Public Hearing to receive testimony regarding the Standards on October 13, 2010, with written testimony being received for an additional seven (7) days after the hearing. Testimony was received from five (5) organizations and is summarized as follows:

1. *Georgia Fojtasek, Allegiance Health*

- Supports continued CON regulation.
- Recommends review of the current minimum volume requirements for OHS.
- In 2009 open heart volumes across the state, 17 of 33 (52%) adult programs fell below the current 300 minimum volume.
- Advises as less invasive options continue to develop open heart volumes will only decrease and even more existing programs will struggle to meet minimum volumes.

2. *Robert Meeker, Spectrum Health*

- Supports continued CON regulation.
- Recommends no review of current OHS Standards as the number of open-heart procedures declined by 14% from 2005-2009 per the Michigan Annual Surveys of Hospitals.

3. *Dennis McCafferty, Economic Alliance for Michigan*

- Supports continued CON regulation.
- Supports the formation of an OHS SAC
- Recommends review of the minimum annual volume requirements.
- Recommends reviewing the standards to facilitate the consolidations and/or closure of OHS programs that consistently fail to meet the minimum annual volumes.

4. *Sean Gehle, The Michigan Health Ministries of Ascension Health*

- Supports the continued CON regulation.
- Recommends no review of current OHS Standards; specifically no formation of a SAC or workgroup at this time.

5. *Jim Gilson, Beaumont Hospitals*

- Supports continued CON regulation.
- Supports the current minimum procedure volume thresholds of 300.
- Requests that “the Commission continue to pressure the Department to routinely and consistently enforce CON regulations, including volume requirements.”

### **Summary of Covered Service**

The Department did not receive any testimony against the de-regulation of Open Heart Surgery. Michigan is one of 27 states which regulate Open Heart Surgery within CON. In 2009, per the CON Annual Survey 12,674 patients underwent open heart surgery within one of the 34 approved facilities.

### **MDCH Staff Recommendations**

- **The Department recommends a three-month postponement of Commission action regarding a decision on a structured review of the Open Heart Surgery Standards. Currently a Cardiac Catheterization Standard Advisory Committee (CCSAC) has been seated and is currently deliberating issues that may have a concomitant effect on the Open Heart Surgery Standards.**
- **The Department proposes to revisit the Standards review question after the Commission and Department have had adequate opportunity to review the direction of the CCSAC.**

### MDCH Recommendations for CON Standards Scheduled for 2011 Review

<b>Positron Emission Tomography (PET) Scanner Services Standards</b> (Please refer to the attached MDCH staff analysis for additional details.)		
Should PET services continue to be regulated under CON?	Yes.	While PET scanners, especially mobile PET scanners, have become increasingly available, PET scanners still require large initial capital investment as well as long term operating expenditures.
Identified Issues	Recommended for Review	Comments
Consider PET standards to specifically address Positron Emission Mammography (PEM)	Yes	The Department will provide the Commission with the recommendations addressing PEM scanner technology in the standards at the March 24, 2011 CON Meeting
Consider refinement to current utilization methodology for replacement and expansion of existing PET scanners and services, respectively.	Yes	Current utilization methodology is labor intensive for existing providers to accurately collect and report to the Department for replacement, expansion and compliance requirements. Also, the current methodology offers little, if any, correlation between required volumes to initiate a PET service and volume requirements to replace an existing unit or expand a current service. Maintenance volume is the same for both fixed and mobile services, yet volume requirements are different for initiation, replacement and expansion. In addition, a review is needed of the appropriateness of the data categories used for initiation (specific cancer diagnoses, diagnostic cardiac catheterization, intractable epilepsy, and possibly front temporal dementia/Alzheimer's). Finally, consideration should be given to allowing commitment of the differential data for those who have committed cases and the 5-year period of operation of the service to which the original data was committed has elapsed (similar to open heart surgery services).
Consider simplification of equipment replacement requirements.	Yes	Existing PET services must meet set volume requirements to replace existing equipment. However, simplification of the replacement requirements with minimal to no volume requirement affords providers the opportunity to replace existing units as newer, better technology becomes available assuring patients receive the best standard of care.
Identified Issues	Recommended	Comments

	<b>for Review?</b>	
Consider minimum volume requirement for host sites receiving mobile PET services.	Yes	Minimum volumes for host sites are required for MRI services to assure sites receive minimum and continuous services. A minimum volume requirement is recommended for PET services to achieve a similar goal as in MRI.
Consider allowing existing host sites to relocate.	Yes	Host sites cannot relocate to a new site, even if the new site serves the same service area and offers lower operating costs. Applicants must reapply as initiating a new host site. Such a relocation provision is important if a minimum volume requirement for host sites is approved.
Consider modifications to Project Delivery Requirements.	Yes	Reduce number of project delivery requirements for approved services that are enforceable, objectively measurable, and achieve major objectives of assuring affordable, quality PET services without overwhelming providers.

## **MDCH Staff Analysis of the PET Scanner Services Standards**

### **Statutory Assignment**

Pursuant to MCL 333.22215 (1)(m), the Certificate of Need (CON) Commission is to "...review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the PET Scanner Services Standards are scheduled for review in calendar year 2011.

### **Public Hearing Testimony**

The Department held a Public Hearing to receive testimony regarding the Standards on October 13, 2010, with written testimony being received for an additional seven (7) days after the hearing. Testimony was received from four (4) organizations and is summarized as follows:

#### *1. Jim Gilson, Beaumont Hospitals:*

- Beaumont Hospitals support the overall regulations of PET Scanner services; however, has some recommendations on items that need to be addressed:
- Would like there to be a review of the weights assigned to "bed positions" due to the variances in PET camera manufacturers.
- Recommends CON regulations provide use of research PET in unanticipated downtime.
- Would like to see review of PET standards to consider making an exemption for the use of Positron Emission Mammography (PEM).



- Contends that the lack of standards or exemption from PET CON standards confines the use of PEM to research protocols and denies comprehensive breast care programs in Michigan from offering women this clinical tool.
2. *Sean Gehle, The Michigan Health Ministries of Ascension Health:*
    - Supports the continued CON regulation.
    - Recommends neither change nor the formation of a SAC.
  3. *Meg Tipton, Spectrum Health Hospitals:*
    - Supports the continued CON regulation.
    - Recommends no change.
    - Contends that current CON standards have assured the availability of sufficient access to PET scanners to meet the needs of Michigan citizens, while enabling health care organizations to provide quality care to patients.
  4. *Tina Weatherwax Grant, Trinity Health*
    - Supports the continued CON regulation.
    - Recommends the formation of a workgroup to propose language that establishes a formal definition of “radiation therapy patient visit,” specifically regarding Section 16 (c).
    - Contends that current standards do not include a definition for radiation therapy patient, and consequently there is opportunity for undercounting and over counting in applying the standards to projects which propose expansion, replacement or initiation of a fixed PET from a mobile route.

### **Summary of Covered Service**

The Department received no testimony for de-regulation of PET scanner services. Michigan is one of 24 states that regulate PET services within CON. In accordance with the 2009 Michigan CON Annual Survey, less than 1% of Michigan’s population received a PET scan (38,033) from the 26 units located within the 70 approved sites throughout the state.

### **MDCH Staff Recommendations**

- **Conduct departmental review of standards with an emphasis to assure uniformity among the various imaging standards, where applicable, and create a user-friendly format.**

**MDCH Staff Recommendations** - continued

- **Conduct departmental review of project delivery requirements. Project delivery requirements are those requirements that a recipient of an approved CON must comply with throughout the life of the services, or unless modified by a subsequent CON approval. Review is to assure that each requirement is measurable, comports with today's standard of care, does not duplicate other regulatory requirements already established, and have cost-effective value in achieving the goals and objectives of the program to assure affordable, quality health care services for both the consumer and provider.**
- **Conduct departmental review to simplify projection and utilization methodologies, where possible, in a manner that is comparable to existing thresholds but reduces the labor-intensive collection process for the provider and potential applicants using readily available data.**
- **Conduct departmental review to simplify replacement requirements for existing providers to replace covered equipment in a more streamlined process that assures consumer access to advance technology.**
- **Conduct departmental review related to PEM scanner technology and existing requirements. Develop, if needed, requirements that assure this technology/service is readily available where needed.**
- **Present proposed draft standards to Commission at the March 24, 2011 meeting.**

## MDCH Recommendations for CON Standards Scheduled for 2011 Review

<b>Surgical Services</b> (Please refer to the attached MDCH staff analysis for additional details.)		
Should the covered service continue to be regulated?	Yes	Surgical services located within a hospital or freestanding facility requires large initial capital investment as well as long term operating costs. Once licensed as a hospital or freestanding surgery center, providers are allowed to include a facility fee when billing for all surgical procedures performed within these sites.
Identified Issues	Recommended Review	Comments
Consider exception for dedicated trauma operating room without volume requirement.	No	Current Standards already provide exception for trauma services at licensed hospitals.
Consider exception for dedicated research operating room without volume requirement.	No	No clear evidence to suggest immediate need for new exception for research operating room.
Consider exception for existing non-licensed vascular centers to initiate surgical services as a federally certified ASC site.	No	Current volume requirements to initiate new FSOF or ASC sites with a single operating room does not present a major barrier to existing vascular centers. The barrier to initiation is not the volume requirement set forth within the standard but specifically that these vascular surgical procedures have not been historically performed in licensed operating rooms.
Consider refinement to current volume requirements for operating rooms.	Yes	Round volume requirements to whole numbers for replacement, expansion and maintenance of operating rooms.
Consider new requirements for procedure rooms on a sterile/restricted corridor in a hospital or freestanding surgery center.	Yes	Procedure rooms on a sterile/restricted corridor can be used and billed as if an operating room. Current standards are vague on prohibiting procedure rooms on sterile/restricted corridors.

Consider new requirements for operating rooms that are equipped with cardiac catheterization equipment.	Yes	With FDA consideration of percutaneous valve replacement/repair, more hospitals are installing cardiac catheterization equipment in operating rooms. These dual purpose rooms may require reduced volume requirements as procedures performed in these rooms will be limited.
Consider modifications to Project Delivery Requirements.	Yes	Reduce number of project delivery requirements for approved services that are enforceable and achieve major objectives of assuring affordable, quality surgical services without overwhelming providers.

## **MDCH Staff Analysis of the Surgical Services Standards**

### **Statutory Assignment**

Pursuant to MCL 333.22215 (1)(m), the Certificate of Need (CON) Commission is to "...review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the Surgical Services Standards are scheduled for review in calendar year 2011.

### **Public Hearing Testimony**

The Department held a Public Hearing to receive testimony regarding the Standards on October 13, 2010, with written testimony being received for an additional 7 days after the hearing. Testimony was received from three organizations and is summarized as follows:

#### *1. Joe Garcia, RMS Lifeline*

- Gave a brief overview of Lifeline Vascular Access in Michigan.
- Requests to change the Certificate of Need Standard so that six clinics that perform procedures to install and maintain catheters and fistulas for kidney dialysis patients are reclassified as ambulatory surgical centers. Maintains this request is because clinics are currently under economic distress because of reductions in physician payments, and that's the only payment which sustains the clinics currently.

#### *2. Meg Tipton, Spectrum Health Hospitals*

- Supports continued regulation of surgical services with the following recommendations:
- Proposes the inventory of hospital operating rooms in a licensed hospital be changed to reflect an allowance for the use of one (1) full-time operating room that could be used exclusively for the purpose of providing trauma care.
- Suggests that the definition for "Trauma Care" mean "surgical services provided to a trauma patient in a licensed hospital site that has been verified as meeting the standards of the American College of Surgeons for a Level I trauma center."

- Suggests “Research” mean “surgical services provided in a room under research protocol approved by the applicant’s IRB.”

3. *Carlos Rodriguez, MD, Spectrum Health Hospitals*

- Supports continued regulation of surgical services with the following recommendation:
- Proposes the Surgical Services Standards be modified to include a provision for a dedicated trauma operating room which could be excluded from the normal CON volume requirements.

4. *Shayam Parekh, Spectrum Health Hospitals*

- Supports continued regulation of surgical services with the following recommendations:
- Proposes a provision be added to the Surgical Services Standards dedicating an operating room for research.
- Contends that with the added provision; more experimentation and innovation would be possible without disrupting the precision and efficient operation of busy perioperative services.
- Further contends the types of research which can be done are limited by the types of operating rooms which are created.

5. *Dennis McCafferty, Economic Alliance for Michigan (EAM)*

- Supports continued regulation of surgical services and the formation of a SAC workgroup.
- Supports changes that would improve proficiency, outcomes, and cost-effectiveness, while addressing relevant access concerns.
- Also supports changes in the standards that would specify surgical support staff of all free-standing surgical centers be credentialed by appropriate national accreditation organizations.

6. *Sean Gehle, The Michigan Health Ministries of Ascension Health*

- Supports continued regulation of surgical services and the formation of a SAC workgroup to address any relevant issues.

### **Summary of Covered Service**

The Department did not receive any testimony against de-regulation of Surgical Services. Michigan is one of 27 states which regulate surgical services within CON. In accordance with 2009 CON Annual Survey, there were 1,286,779 surgical procedures performed within one of the 1,343 approved operating rooms at the 246 hospitals that offer this covered service.

### **MDCH Staff Recommendations:**

- **Conduct departmental review of standards with an emphasis to assure uniformity among the various standards, where applicable, and create a user-friendly format.**
- **Conduct departmental review of project delivery requirements. Project delivery requirements are those requirements that a recipient of an approved CON must comply with throughout the life of the services, or unless modified by a subsequent CON approval. Review is to assure that each requirement is measurable, comports with today's standard of care, does not duplicate other regulatory requirements already established, and have cost-effective value in achieving the goals and objectives of the program to assure affordable, quality health care services for both the consumer and provider.**
- **Conduct departmental review to simplify projection and utilization methodologies, where possible, in a manner that is comparable to existing thresholds but reduces the labor-intensive collection process for the provider and potential applicants using readily available data.**
- **Conduct departmental review to simplify replacement requirements for existing providers where the site of the surgical service will not change, only the location of the operating room within the existing site changes.**
- **Present proposed draft standards to Commission at the September 22, 2011 meeting.**



# **Vascular Access Procedure Cost Comparison by Place of Service**

**January, 2011**

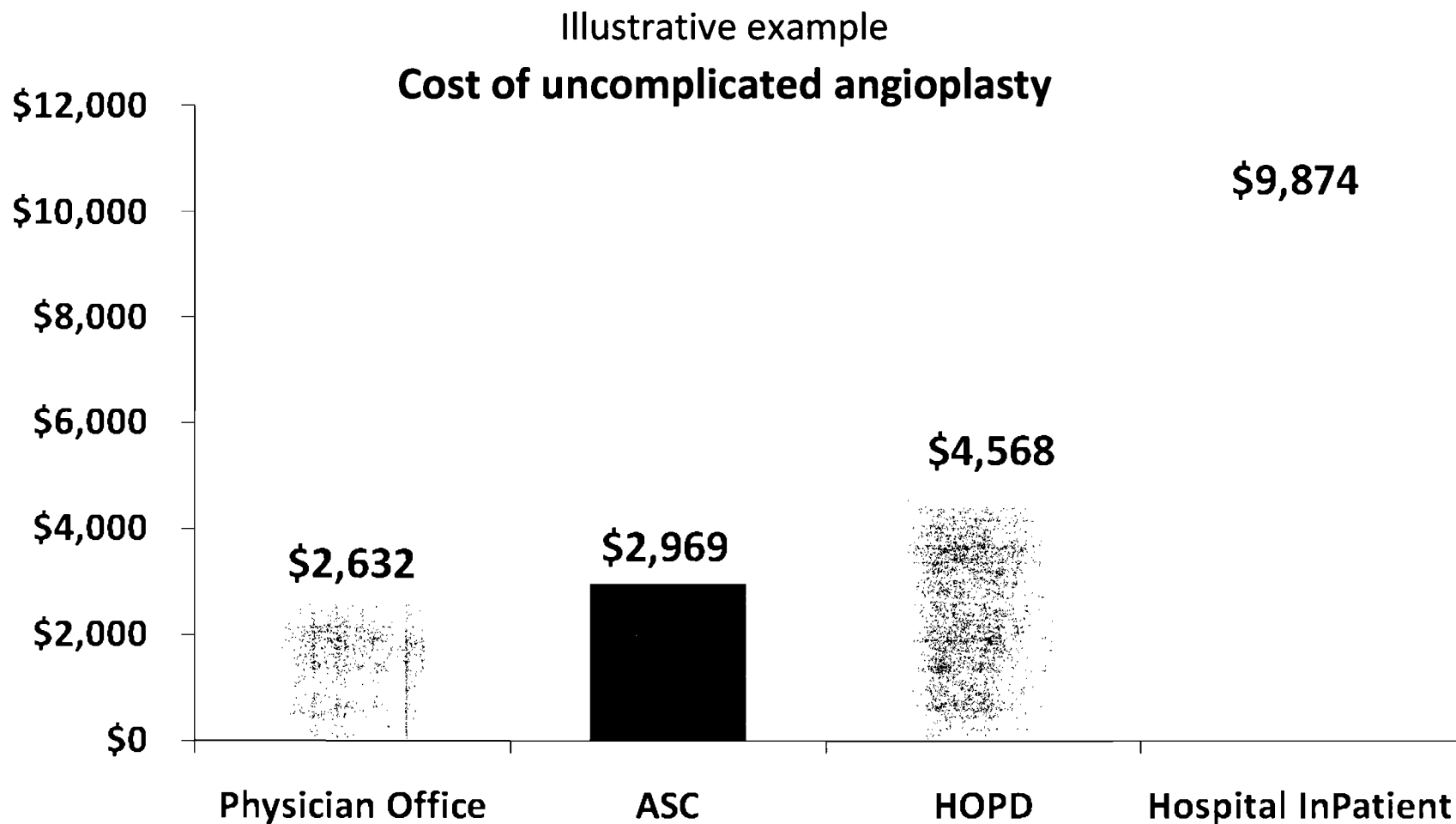
## Procedure cost comparison by POS

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- ESRD patients treated at VACs (i.e. Physician Office) cost less than those treated at other sites of service (i.e. HOPD and Hospital Inpatient)
  
- Treatment at ASCs cost less than HOPD or Hospital Inpatient
  
- Illustrative examples are provided for 4 scenarios that make up ~65% of Physician Office case mix
  - Angioplasty (35%)
  - Thrombectomy (13%)
  - Catheter Exchange (11%)
  - Catheter Placement (6%)



# Angioplasty cost comparison

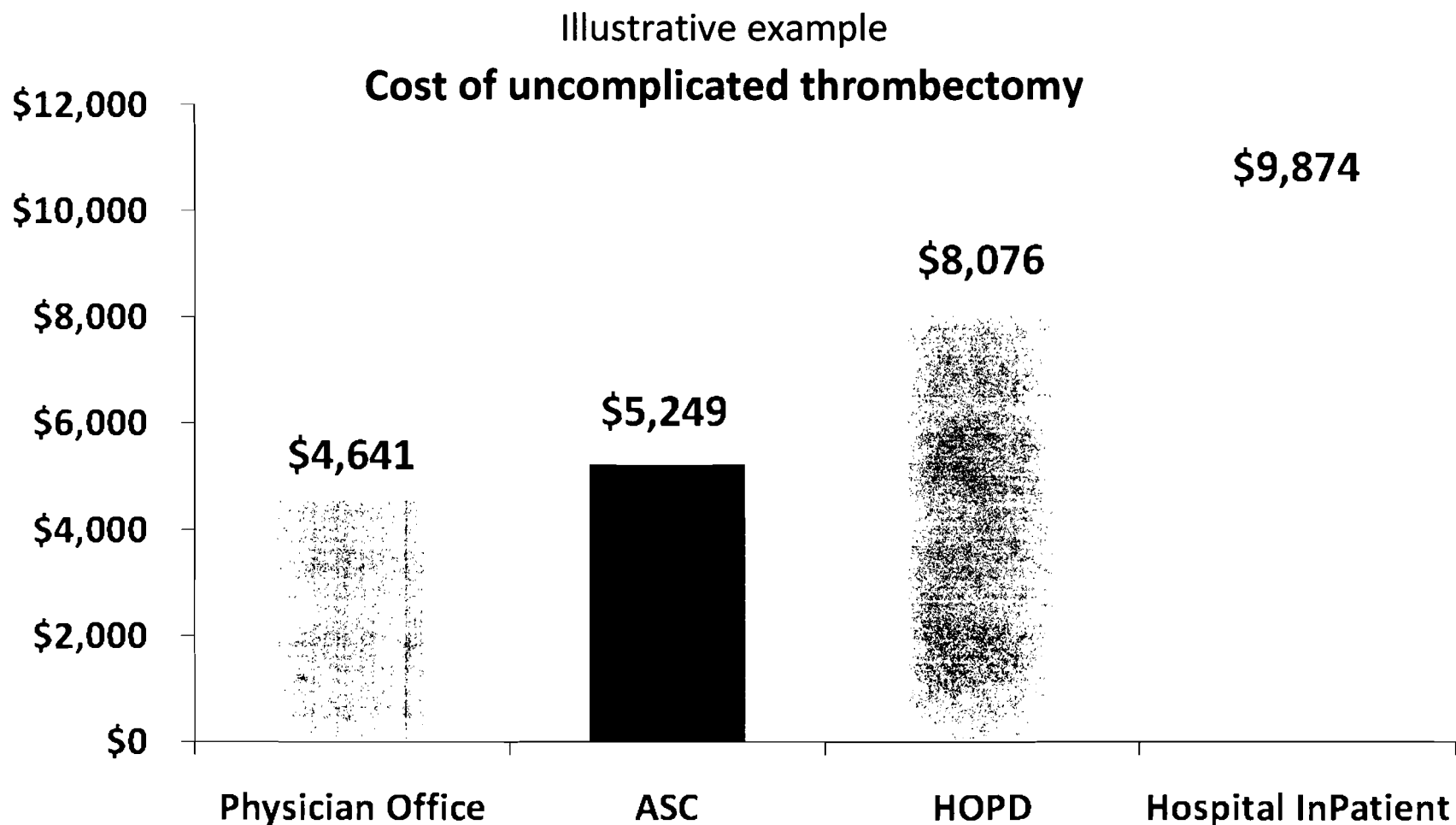


Original Data Source: CMS Data

Secondary Data Sources: 1) Boston Scientific 2010 Procedural Reimbursement Guide, 2) Cook Medical 2010 Coding and Reimbursement Guide3)

Lifeline Analysis

# Thrombectomy cost comparison

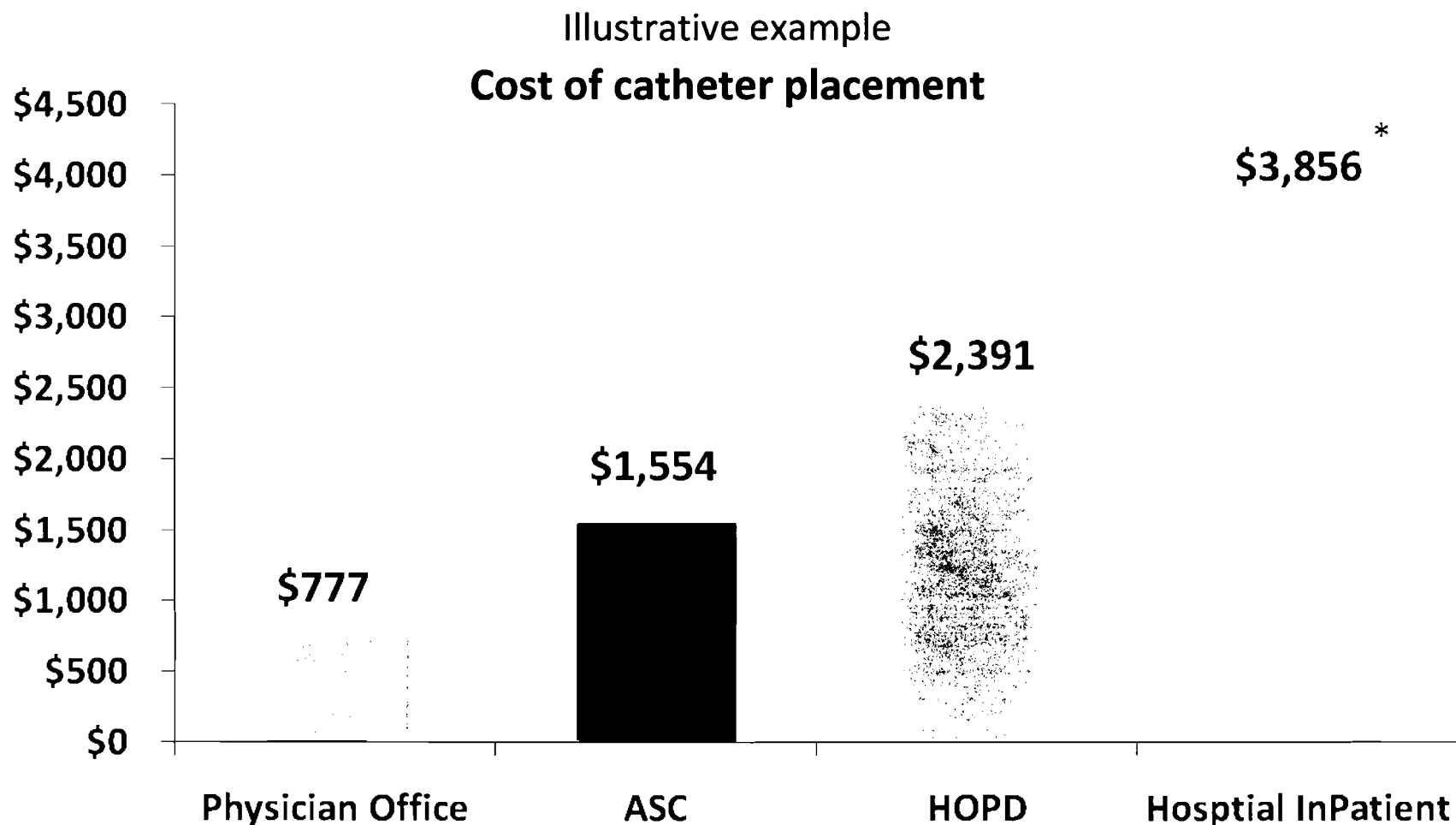


Original Data Source: CMS Data

Secondary Data Sources: 1) Boston Scientific 2010 Procedural Reimbursement Guide, 2) Cook Medical 2010 Coding and Reimbursement Guide3)

Lifeline Analysis

# Catheter placement cost comparison



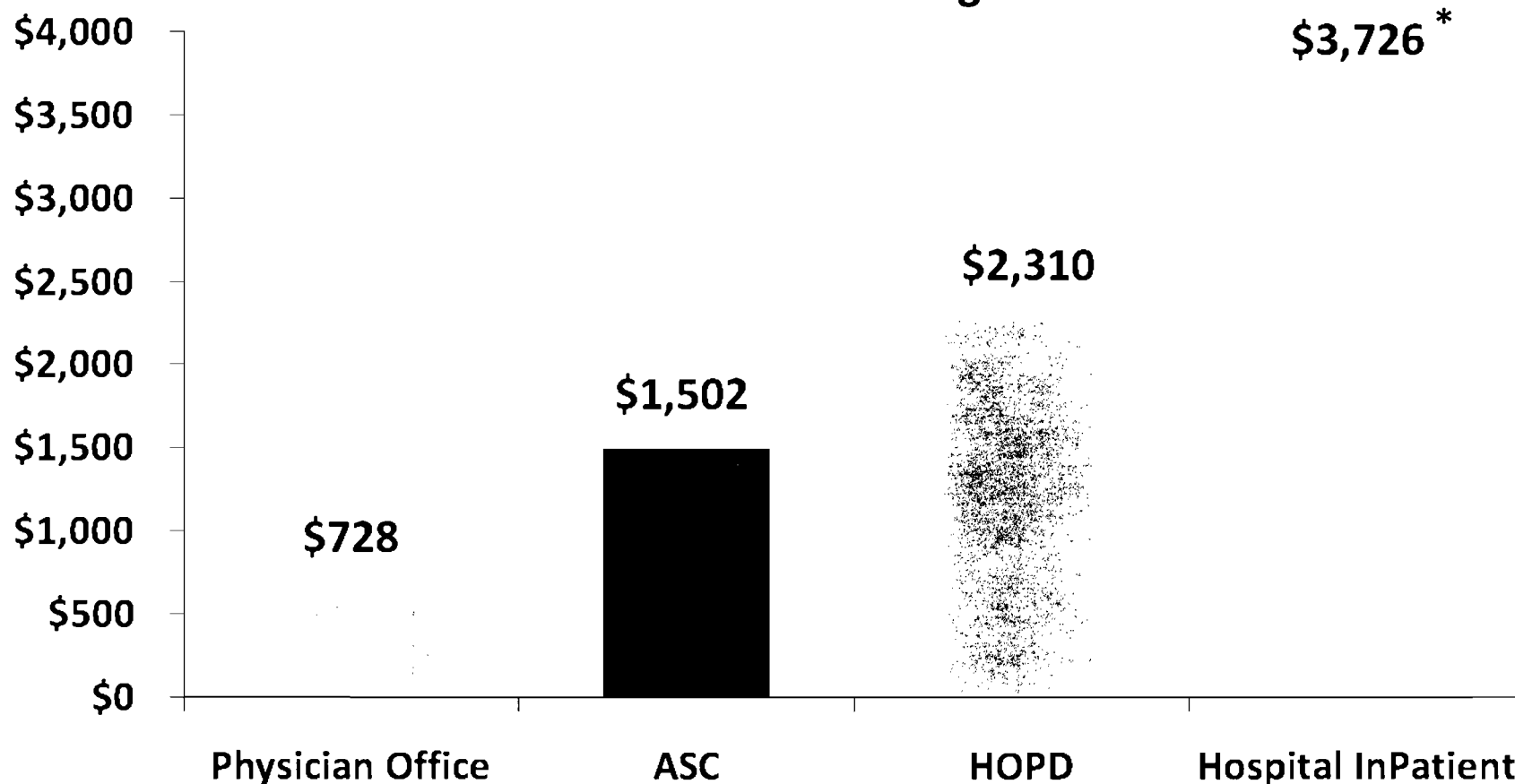
\* Based on HOPD costs assuming  
HOPD is 62% of Hospital InPatient

Original Data Source: CMS Data

Secondary Data Sources: 1) Boston Scientific 2010 Procedural Reimbursement Guide, 2) Cook Medical 2010 Coding and Reimbursement Guide3)  
Lifeline Analysis

# Catheter exchange cost comparison

Illustrative example  
**Cost of catheter exchange**



\* Based on HOPD costs assuming HOPD is 62% of Hospital InPatient

Original Data Source: CMS Data

Secondary Data Sources: 1) Boston Scientific 2010 Procedural Reimbursement Guide, 2) Cook Medical 2010 Coding and Reimbursement Guide3)

Lifeline Analysis

# Summary

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## *VAC or ASC Cost Less Than HOPD or Hospital Inpatient*

- Patients treated at ASC or free standing access center cost significantly less than if treated at HOPD or as Hospital Inpatients
- ASC payment rates for the most part are approximately 65% of Medicare outpatient APC hospital rates for the same procedure

**The Certificate of Need (CON) Commission Should Change the Surgical Services  
CON Standards to Enable Surgeons to Acquire a CON to Initiate a New Spine-  
Focused Ambulatory Surgery Center**

Presenter: Jeffrey R. Schell, Esq.  
Representing Saginaw Valley Neurosurgery, PLLC, Saginaw, Michigan  
January 26, 2011

**Background: The Development of Outpatient Spine Surgeries**

Recent advances in outpatient anesthesia combined with new surgical techniques for minimally invasive spinal surgery have dramatically affected how such surgeries can be performed. Technological advances in operating room equipment mean that many of these surgical procedures are now being performed safely in outpatient centers throughout the country and world. [1-11] Peer reviewed literature provides ample evidence for performing many types of spinal surgery in the outpatient arena with lower complication rates and higher patient and payer satisfaction. [12, 13] As recently as December 2010, the peer-reviewed *Journal of Clinical Neuroscience* presented findings that spine surgeries performed in outpatient environments led to at least the same, but in many cases, significantly better patient outcomes than spine surgeries performed in inpatient environments. [14]

Spinal disorders including back and neck pain with or without associated arm and leg pain are very common. Back pain is the second most common reason for physician visits in the United States and accounts for 200 million person days of lost work each year. One in four U.S. adults will suffer with back pain in any given three-month period. Musculoskeletal medicine is the leading cause of disability in the U.S. with “back” symptoms as the leading cause of job-related disability. Patients with back pain incur substantially higher (> 50%) health care costs than individuals without back pain. The number of U.S. adults suffering from musculoskeletal disorders continues to grow with annual costs for bone and joint health in the U.S. soaring at \$850 billion.[15]

Many other states have allowed surgeons to develop spine ambulatory surgical centers (ASCs) to address spinal problems requiring surgery. Spine surgery in ASCs reduces costs to payors and improves outcomes and convenience for patients. Spine ASCs attract the best physicians to the states that allow them. Michigan is facing a critical shortage of physicians of all specialties, particularly spine surgeons. Saginaw Valley Neurosurgery, which regularly operates on patient backlogs of 8 weeks or more, has engaged in ongoing efforts to recruit spine surgeons to Michigan and has encountered great difficulty. One of the key reasons surgeons focusing on spine do not wish to come to Michigan is because they do not have the opportunity to direct and control an outpatient spine surgery facility, as they do in other states.

## Why Michigan's "Surgical Services" CON Standards Block the Important Benefits Associated with Spine ASCs

The methodology associated with the current CON standards to initiate a surgical service is flawed. To receive a CON, physicians must generally "pledge" 1,128 cases to initiate a surgical service, with generally no consideration the type of surgical cases pledged. This system favors and rewards surgeons of less complex specialties, who can accomplish a high volume of surgeries in a short period of time. This system punishes surgeons who focus on spine, who perform fewer, more complex cases over comparable periods of time. This structure costs Michigan's patients and payors money, since surgeons could lower payor costs by thousands of dollars per procedure if they performed spine cases in an ambulatory surgery center (ASC), without sacrificing quality or deteriorating patient outcomes.

Under the standards as currently written, a physician performing dental, urology, gastroenterology, or pain-related surgical services can much more easily demonstrate the needed case volume than a surgeon focusing on spinal procedures. For example, under the "Surgical Services" CON Standards' methodology, a pledged dental or a pain case performed in a surgery center counts for the same as a much more complex spinal fusion. This outdated case-pledging structure is a relic of the time where outpatient spine surgeries were unfathomable.

The circumstances have since changed. The current standards fail to account for the cost savings or increased patient benefits currently possible with Spine ASCs. The CON Commission can address this problem by revising the "Surgical Services" CON standards to allow a surgeon to own and operate a spine-focused ASC in Michigan. The very high costs of common spinal procedures remain artificially inflated in Michigan directly as a result of the current "Surgical Services" CON standards, which effectively prevent specialized surgeons from developing spine ASCs.

Spine ASCs in other states have substantially reduced costs to payors associated with spine surgeries, which include some of the most expensive medical procedures. They do so while providing a level of patient care that is equal to or better than inpatient spine surgical care. The cost savings associated with spine surgeries performed in ASCs is dramatic. For comparison, less complex procedures such as dental or pain procedures can cost \$500 or less. Spine procedures rarely cost less than \$15,000, and can often cost as high as \$50,000-\$75,000. According to surgery center officials in other states, based on actual EOBs obtained from patients, it is 50%-66% cheaper to commercial payors to reimburse outpatient spine surgery compared with inpatient spine surgery reimbursements.[16]

The "Surgical Services" CON standards, which emphasize raw case volume without accounting for the complexity of the cases performed, create unequal difficulty for lower-volume surgeons that focus on more highly complex spine surgeries. While less complex surgical procedures often allow 30 or more cases to be performed in a day, most surgeons would consider an operating room day with 5 spine cases to be a full day. Therefore, surgeons focusing on spine do not have the capacity to pledge the cases necessary to obtain a CON for surgical services in Michigan, by the very nature of the greater requirements of the care they provide.

While spine surgeons would like to cooperate with other entities to obtain “Surgical Services” CONs, insurmountable barriers prevent them from doing so. Hospitals do not wish to cooperate with spine surgeons who would establish outpatient spine surgery centers. These hospitals have economic disincentives to allow spine surgeons to perform spine surgery cases at lower-cost outpatient facilities. Also, non-spine physicians who own other ASCs remain hesitant to allow spine surgeons to effect the changes to the infrastructure of their own ASCs. Neurosurgeons and Orthopedic Surgeons who focus on spine would need to direct major changes and develop protocols and programs within existing ASCs to make them effective for spine cases. Existing ASCs generally do not wish to cede such control.

Thus, given the nature of the services they offer, surgeons who focus on spine have a tremendous disadvantage when attempting to partner with other entities to meet the CON requirements. Further, given the increased complexities associated with and increased time requirements for spine procedures, such surgeons cannot independently meet the volume requirements for spine surgical procedures under the CON standards to initiate surgical services as currently written. As a result, patients do not have opportunities to receive higher quality outpatient spine surgical care, and payors have no choice but to pay the significantly higher inpatient fees for surgical care in Michigan.

Therefore, to reap the significant cost and patient care benefits associated with outpatient spine procedures, and to reflect the changed circumstances surrounding spine cases, it is vital for the Certificate of Need Commission to revise the “Surgical Services” CON standards. The revisions should take into account the unique and disproportionate challenges neurosurgeons and orthopedic spine surgeons face with regard to the CON Standards related to the initiation of Spine ASCs, and the benefits to patients and payors associated with Spine ASCs. The revisions should ultimately enable such surgeons to initiate new surgical services at new Spine ASCs.

**The revisions should:**

- 1. Lower the volume requirements in the CON standards to initiate Surgical Services for surgeons who focus on spine to approximately 100-200 spine cases per room.** This would reflect the increased amount of time per case such surgeons spend relative to less complex surgical specialties.
- 2. Enable spine cases that were performed in a inpatient environments, but were appropriate for a Spine ASC, to be pledged to acquire a CON to initiate Surgical Services.** This would account for the recent technological advances related to minimally invasive spine technologies, which now allow many surgeries currently only performed in inpatient environments in Michigan to be performed in outpatient Spine ASCs.



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**CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN**

	2010												2011											
	J*	F	M*	A	M	J*	J	A	S*	O	N	D*	J*	F	M*	A	M	J*	J	A	S*	O	N	D*
Cardiac Catheterization Services**			•	•	•	•	•	•	•	PH	■	■	■	■	■	■	■	•R—	•	•P	•▲F			
Computed Tomography (CT) Scanner Services**	•R	•	•	•			■	■	■	■	■	■	■	•	—	•	•P	•▲F						
Hospital Beds and Addendum for HIV Infected Individuals										PH•	•	•	•R											
Magnetic Resonance Imaging (MRI) Services									•R—	P•	•	•▲F	•	•	•R									
Megavoltage Radiation Therapy (MRT) Services/Units										PH	•	•	•R											
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	•R	•	•	•	•	R•	•	•	•R—	P•	•	•▲F												
Open Heart Surgery Services										PH	•	•	•R											
Positron Emission Tomography (PET) Scanner Services										PH	•	•	•R											
Surgical Services										PH	•	•	•R											
Renewal of "Guiding Principles for Determining Whether a Clinical Service should Require Certificate of Need (CON) Review"																								
New Medical Technology Standing Committee	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M
Commission & Department Responsibilities			M			M			M			M			M			M			M			M

**KEY**

- - Receipt of proposed standards/documents, proposed Commission action
- \* - Commission meeting
- - Staff work/Standard advisory committee meetings
- ▲ - Consider Public/Legislative comment
- \*\* - Current in-process standard advisory committee or Informal Workgroup
- - Staff work/Informal Workgroup/Commission Liaison Work/Standing Committee Work
- A - Commission Action
- C - Consider proposed action to delete service from list of covered clinical services requiring CON approval
- D - Discussion
- F - Final Commission action, Transmittal to Governor/Legislature for 45-day review period
- M - Monitor service or new technology for changes
- P - Commission public hearing/Legislative comment period
- PH - Public Hearing for initial comments on review standards
- R - Receipt of report
- S - Solicit nominations for standard advisory committee or standing committee membership

Approved December 15, 2010

Updated December 15, 2010

The CON Commission may revise this work plan at each meeting. For information about the CON Commission work plan or how to be notified of CON Commission meetings, contact the Michigan Department of Community Health, Health Policy & Regulation Administration, CON Policy Section, 7th Floor Capitol View Bldg., 201 Townsend St., Lansing, MI 48913, 517-335-6708, [www.michigan.gov/con](http://www.michigan.gov/con).

**SCHEDULE FOR UPDATING CERTIFICATE OF NEED (CON) STANDARDS EVERY THREE YEARS\***

<b>Standards</b>	<b>Effective Date</b>	<b>Next Scheduled Update**</b>
Air Ambulance Services	August 12, 2010	2013
Bone Marrow Transplantation Services	December 3, 2010	2012
Cardiac Catheterization Services	February 25, 2008	2011
Computed Tomography (CT) Scanner Services	June 20, 2008	2013
Heart/Lung and Liver Transplantation Services	May 28, 2010	2012
Hospital Beds and Addendum for HIV Infected Individuals	March 2, 2009	2011
Magnetic Resonance Imaging (MRI) Services	November 5, 2009	2012
Megavoltage Radiation Therapy (MRT) Services/Units	November 13, 2008	2011
Neonatal Intensive Care Services/Beds (NICU)	August 12, 2010	2013
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	June 20, 2008	2013
Open Heart Surgery Services	February 25, 2008	2011
Pancreas Transplantation Services	November 5, 2009	2012
Positron Emission Tomography (PET) Scanner Services	March 8, 2007	2011
Psychiatric Beds and Services	November 5, 2009	2012
Surgical Services	June 20, 2008	2011
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	February 25, 2008	2013

\*Pursuant to MCL 333.22215 (1)(m): "In addition to subdivision (b), review and, if necessary, revise each set of certificate of need review standards at least every 3 years."

\*\*A Public Hearing will be held in October prior to the review year to determine what, if any, changes need to be made for each standard scheduled for review. If it is determined that changes are necessary, then the standards can be deferred to a standard advisory committee (SAC), workgroup, or the Department for further review and recommendation to the CON Commission. If no changes are determined, then the standards are scheduled for review in another three years.