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

Thursday, January 28, 2010

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 at 9:37 a.m.

A. Members Present:

Edward B. Goldman, Chairperson
Peter Ajluni, DO (on the phone, left at 11:30 a.m.)
Bradley Cory
James B. Falahee, Jr., JD
Marc Keshishian, MD (left at 1:15 p.m.)
Michael A. Sandler, MD
Thomas M. Smith, Vice-Chairperson
Michael W. Young, DO (arrived at 9:48 a.m.)

B. Members Absent:

Dorothy E. Deremo
Adam Miller
Vicky Schroeder

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Community Health Staff Present:

Jessica Austin
Michael Berrios
Tulika Bhattacharya
William Hart
Irma Lopez
Kasi Kelley
Joette Laseur
Nick Lyon
Andrea Moore
Tania Rodriquez
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Cory, seconded by Commissioner Sandler, to insert a public comment before item XIII and then to approve agenda as modified. Motion Carried.

III. Declaration of Conflicts of Interest

None.

IV. Review of Minutes – December 9, 2009

Motion by Vice-Chairperson Smith, seconded by Chairperson Falahee, to approve the minutes of December 9, 2009 as presented. Motion Carried.

V. Air Ambulance Services

A. Public Hearing Summary & Report:

Ms. Rogers gave an overview of the Public Hearing summary and gave the Department's recommendation. (Attachment A)

B. Public Comment:

Sean Gehle, St. John's Health System

C. Commission Discussion:

None.

D. Commission Proposed Action:
Motion by Vice-Chairperson Smith, seconded by Commissioner Keshishian, to approve the Department's recommendation. Motion Carried.

VI. Computed Tomography (CT) Scanner Services

A. Public Hearing Summary & Report:

Ms. Rogers gave an overview of the Public Hearing summary and gave the Department's recommendation. (Attachment B)

B. Public Comment:

Larry Horwitz, Economic Alliance of Michigan
Caroline Ruddell, Michigan Dental Association (Attachment C)
Amy Barkholz, Michigan Hospital Association
Keith Haines, Neurologica (Attachment D- http://www.michigan.gov/mdch/0,1607,7-132-2945_5106_5409_29279-208666--,00.html)
Barbara Jackson, Blue Cross Blue Shield of Michigan
Bob Meeker (for Lody Zwarensteyn), Alliance for Health
Sean Gehle, Ascension Health

C. Commission Discussion:

Discussion followed.

E. Commission Proposed Action:

Motion by Commissioner Sandler, seconded by Commission Keshishian, to adopt department's recommendation to provide a report at the next commission meeting. Yes – 4, No – 4, Abstained – 0. Motion Failed.

Motion by Commissioner Sandler, seconded by Commissioner Keshishian, to create a Standards Advisory Committee (SAC) for the CT Services and delegate writing/approval of the charge to the Chairperson and Vice-Chairperson. Yes – 7, No – 0, Abstained – 0. Motion Carried.

VII. Nursing Home & Long Term Care Services

A. Ms. Rogers gave an overview of the Public Hearing summary and gave the Department's recommendation. (Attachment E)

B. Public Comment:

Bob Meeker (for Lody Zwarensteyn), Alliance for Health
Sean Gehle, Ascension Health
Stephanie Shooks (Did not wish to speak), (Attachment F)
Barbara Jackson, Blue Cross Blue Shield of Michigan
Pat Anderson, Healthcare Association of Michigan

D. Commission Discussion:

None.

E. Commission Proposed Action:

Motion by Commissioner Cory, seconded by Vice-Chairperson Smith, to accept the Department's recommendation. Yes – 7, No – 0, Abstained – 0. Motion Carried.

Recessed at 11:00 a.m. and reconvened at 11:20 a.m.

VIII. Neonatal Intensive Care Services/Beds (NICU)

A. Ms. Rogers gave an overview of the Public Hearing summary and gave the Department's recommendation. (Attachment G)

B. Public Comment:

Barbara Jackson, Blue Cross Blue Shield of Michigan
Sean Gehle, Ascension Health

C. Commission Discussion:

None.

D. Commission Proposed Action:
Motion by Commissioner Falahee, seconded by Commissioner Young, to accept the Department's recommendation. Yes – 7, No – 0, Abstained – 0. Motion Carried.

IX. Urinary Extracorporeal Shock Wave Lithotripsy Services/Units

A. Ms. Rogers gave an overview of the Public Hearing summary and gave the Department's recommendation. (Attachment H)

B. Public Comment:

Jorgen Madsen, Great Lakes Lithotripsy (Attachment I)
Bob Meeker, Spectrum Health
Bob Meeker (for Lody Zwarensteyn), Alliance for Health
Sean Gehle, Ascension Health
Karen Kippen, Henry Ford Health System
Andy Ball, Oakwood Hospital
Amy Barkholz, Michigan Hospital Association
Dennis McCafferty, Economic Alliance of Michigan
Larry Horwitz, Economic Alliance of Michigan

C. Commission Discussion:

Discussion followed.

D. Commission Proposed Action:

Motion by Commissioner Falahee, seconded by Commissioner Young, to accept the Department's recommendation and have the Department provide a report at the March meeting. Yes – 7, No – 0, Abstained – 0. Motion Carried.

X. Cardiac Catheterization Services and Open Heart Surgery Services

A. Public Comment:

Cheryl Miller, Trinity Health (Attachment J)
Michael Jaggi, Hurley Medical
Barbara Jackson, Blue Cross Blue Shield of Michigan
Dan Witt, Metro Health Hospital
Sean Gehle, Ascension Health (Attachment K)
Bob Meeker, Spectrum Health
Bob Meeker (for Lody Zwarensteyn), Alliance for Health
Terry Gerald, Detroit Medical Center
Susan Heck, Hurley (Carazon) Medical Center
Jamal Ghani, Hurley Medical Center
Dennis McCafferty, Economic Alliance

C. Commission Discussion:

Discussion followed.

D. Commission Action:

Motion by Commissioner Sandler, seconded by Commissioner Young, to seat a SAC for Cardiac Catheterization in the Fall of 2010. Yes – 7, No – 0, Abstained – 0. Motion Carried.

XI. CON Commission Bylaws

A. Mr. Potchen gave a written & oral summary of bylaws. (Attachments L and M)

B. Discussion:

Discussion followed.

C. Commission Action:

Motion by Vice Chairperson Smith, seconded by Commissioner Young, to recommend adding public comment to item XII. Yes – 7, No – 0, Abstained – 0. Motion Carried.

Motion by Commissioner Sandler, seconded by Commissioner Keshishian, to approve the Bylaws with the following amendment: remove last sentence on page 7, Article VI, A. Yes – 7, No – 0, Abstained – 0. Motion Carried.

D. Public Comment:

Larry Horwitz, Economic Alliance

XII. Review the Commission Work Plan

Ms. Rogers gave a brief summary of the Work Plan and adding the decisions approved by the Commission. (Attachment N)

A. Public Comment:

Bob Meeker, Spectrum Health
Carol Christner, Karmanos Cancer Institute
Larry Horwitz, Economic Alliance

B. Commission Discussion:

Discussion followed.

C. Commission Action:

Motion by Commissioner Falahee, seconded by Commissioner Sandler, to approve the Work Plan as presented. Yes – 7, No – 0, Abstained – 0. Motion Carried.

XIII. Future Meeting Dates

March 25, 2010
June 10, 2010
September 23, 2010
December 15, 2010

XIV. Adjournment

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

MDCH Recommendations for CON Standards Scheduled for 2010 Review

Air Ambulance Services (Please refer to the attached MDCH staff analysis for additional details.)			
Should the covered service continue to be regulated?	The necessity for regulation should continue to be evaluated.		
All Identified Issues	**Issues Recommended as Requiring Review**	**Recommended Course of Action to Review Issues**	**Other/Comments**
1. Address the draft language for final action which was previously tabled.	Yes.	The draft language should be reviewed and re-evaluated taking into consideration newly received testimony to establish a course of action.	Currently, the Department is applying the existing Standards and is applying the Declaratory Ruling as appropriate.
Recommendation: **The Department recommends no modification to the Standards at this time. A report and recommendation on the pending language changes will be presented to the Commission at a later date.**			

Health Policy Section
Revised 01/25/10
Andrea L. Moore

MDCH Staff Analysis of the Air Ambulance (AA) Services Standards

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 AA Services Standards are scheduled for review in calendar year 2010.

Public Hearing Testimony

The Department held a Public Hearing to receive testimony regarding the Standards on October 20, 2009, 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. Midwest Medflight
   - Provided comment to the proposed Standards approved by the Commission on June 27, 2007. Continues to support most proposed modifications, with the exception of the criteria to change a base of operations.
   - Recommends evaluating the need for any additional Air Ambulances in Michigan due to under-utilization of current resources and the present economic situation.

2. Spectrum Health Hospitals
   - Recommends no modification to the Standards until an opinion is received from the Attorney General addressing the outstanding legal questions to these Standards.

3. University of Michigan Health Systems
   - Provided comment to the proposed Standards approved by the Commission on June 27, 2007. Recommends modification to the definitions of air ambulance service, initiate air ambulance service, and organ transplant; the criteria for expansion of service and the base of operations.
   - Recommends evaluating the need for any additional Air Ambulances in the lower peninsula of Michigan. Contends that this area has complete coverage.

Historical Commission Action

In accordance to the Commission Workplan, the AA Services Standards were reviewed in 2007. The following is a brief outline of the activity and outstanding issues from the 2007 review:

January 9, 2007 Public Hearing

- The Department held a public hearing to receive public input on these Standards. Testimony was received from five (5) organizations.

March 13, 2007 Commission Meeting

- The Commission charged an informal workgroup to evaluate the definitions of patient transport, and primary and secondary service area; and the criteria for expansion of service and replacement of service.

April and May 2007 Informal Workgroup Meetings

- The AA Services Informal Workgroup met two (2) times to address the issues identified by the Commission. Draft language was prepared for Commission review.

June 13, 2007 Commission Meeting

- The Commission reviewed the AA Services Informal Workgroup recommendations and draft language. The Commission took proposed action and moved the draft language forward to public hearing.

August 1, 2007 Public Hearing

- The Department held a public hearing to receive testimony on the proposed changes to the AA Services Standards. Testimony was received from five (5) organizations.

September 18, 2007 Commission Meeting

- The Commission reviewed the public hearing comments and the language for final action.
- The Attorney General's office provided division legal advice on the Declaratory Ruling 2002/01 and Federal preemption of the State's ability to continue regulation of AA Services. This was not a formal opinion from the Attorney General's office.
- The Commission tabled final action on the proposed AA Services Standards pending a formal opinion from the Attorney General's office.

Regulation of the Covered Service

At the September 18, 2007 Commission meeting, the Attorney General's office provided division legal advice on the declaratory ruling and the ability to continue regulation of AA Services. This was not a formal opinion from the Attorney General's office. AA Services are regulated by 7 of the 37 CON States. The issue of continued regulation should be addressed.

2008 AA Service Data

The Department collected AA data via the web-based annual survey in 2008. There were nine (9) providers with a total of 11 primary air ambulances. There were a total of 6,346 patient transports, of which 20% or 1,205 transports were pre-hospital transports and 80% or 5,096 transports were inter-facility transports. The 2008 data by facility is as follows:

2008 AA Service Data

Facility Name	Facility No.	Number of Units	Number of Backup Units	Pre-Hospital Transports	Inter-Facility Transports	Total PT Transports
University of Michigan	81-0060	2	1	101	671	772
Spectrum Health	41-0040	1	1	75	316	391
West MI Air Care	39-1013	1	1	97	516	613
EMS of Saginaw	73-8653	1	1	61	359	420
LifeNet	73-C005	1	0	68	338	406
Toledo Hospital (Promedica)	99-0002	1	5	66	587	653
North Flight	28-C001	1	1	104	163	267
MidWest Medflight	81-1007	1	1	35	347	382
St. Vincent Med Ctr (LifeFlight)	99-1006	2	0	643	1,799	2,442
Statewide Totals for 2008		**11**	**11**	**1,250**	**5,096**	**6,346**

MDCH Staff Recommendations

The Department recommends no modification to the Standards at this time. A report and recommendation on the pending language changes will be presented to the Commission at a later date.

MDCH Recommendations for CON Standards Scheduled for 2010 Review

Computed Tomography (CT) Standards (Please refer to MDCH staff summary of comments for additional detail - attached)			
Should CT services continue to be regulated under CON?	Yes.		There is ongoing debate in the field regarding radiation safety concerns as well as concerns of potential proliferation of units. Therefore, there continues to be a need to monitor and to evaluate these issues.
All Identified Issues	**Issue Recommended for Review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
1. Definition of CT Scanner.	Yes.	None.	Additional information is needed to assess whether the current language reflects the original intent of the Commission.
2. Allowance of Portable Point of Care and Mini CT scanners	Yes.	The Department will continue to evaluate the use of portable point of care and mini CT scanners and will report back to the Commission.	A concern raised is the potential for escalation of the utilization/proliferation of units.
3. Allowance of research only CT scanner language.	Yes.	Determine if appropriate for deliberation by the Commission or for a Department recommendation.	Currently, an applicant proposing a dedicated fixed research CT scanner must meet the same initiation requirements that are applied to regular CT scanners. There is not a separate section of requirements for dedicated research only scanners like there is for MRI & PET standards.
4. Replacement and Relocation language.	No.	None.	There was no rationale provided to support why restrictions should be loosened. No information is given regarding impact on statewide policy.
5. Consistency of language between Standards and Public Health Code.	Yes.	MDCH to review initiation language and if necessary draft language consistent with the Public Health Code.	
6. Make technical changes and updates that provide uniformity in all CON standards, i.e., revisions to reference of online system.	Yes.	MDCH to offer recommendations.	
Recommendation: MDCH recommends that the Commission consider the necessity of addressing the identified issues, and further recommends that the issues to be addressed be referred to the Department for additional review. **MDCH can provide recommendations regarding items 2, 3, 5, and 6 at a future meeting.**			

MDCH Staff Analysis of the Computed Tomography (CT) Standards

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 CT Services Standards are scheduled for review in calendar year 2010.

Public Hearing Testimony

The Department held a Public Hearing to receive testimony regarding the Standards on October 20, 2008, 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. *Steven Szelag, University of Michigan Health System (UMHS):*
    - UMHS supports the overall regulations of CT services; however, has some recommendations on items that need to be addressed:
        - Currently the definition of CT scanner exempts CT scanners from being used in conjunction with several select modalities such as Linear Accelerators.
        - Would like the standards to allow applicants the opportunity to acquire research CT scanners as allowed in MRI and PET.
        - Existing CON standards for replacement and relocation of CT scanners are restrictive and may not adequately meet the specific needs of the applicant.
        - Would like to see more consistency in the definitions contained within the CON standards and the definitions contained within the Public Health Code. Provides example of differences of definition of initiation of CT scanner service between the standards and the Public Health Code.
2. *Barbara Jackson, Blue Cross Blue Shield of Michigan/Blue Care Network (CBSM/BCN):*
    - BCBSM and BCN have concerns of proliferation of CT services in the state of Michigan as well as escalating utilization volumes.
    - Proposes that the standards be thoroughly evaluated and the Commission convene a SAC to do so.
3. *Hon Jin Chang, NeuroLogica Corporation:*
    - Requesting that a permanent alternative to the fixed CT scanner CON standards be established for portable/point of care CT scanners.

- NeuroLogica is the manufacturer for the world's first portable multi-slice CT scanner designed for head and neck imaging.
- The current CON requirements for the State of Michigan prohibit this technology from reaching those patients that need it most.

Regulation of Covered Service

The Department did not receive any testimony for or against the continued regulation of CT Services. Michigan is one of 13 states which regulate CT Services within CON.

CT Survey Data for 2008

Currently, based on the 2008 Annual Survey data, there are 363 fixed CT units in the State of Michigan. Additionally, there are four (4) mobile CT units in the State as well.

In 2008 there were 2,487,314 scans provided by hospitals, freestanding facilities, and host sites. Additionally in 2008, there were 6,021 scans provided by mobile providers.

Definition of a CT Scanner

The Department received testimony from one (1) organization stating that the current definition exempts CT scanners from being used in conjunction with several select modalities such as Linear Accelerators. This organization "believes CT scanners and other imaging modalities, when used in a subsidiary capacity, with any therapeutic and/or diagnostic modality should be exempted from volume driven methodologies."

Section 2(1)(i) of the standards, states that a CT scanner means x-ray CT scanning systems capable of performing CT scans of the head, other body parts, or full body patient procedures including the use of Positron Emission Tomography (PET)/CT scanner hybrids if used for CT procedures only. The term does not include emission-computed tomographic systems utilizing internally administered single-photon gamma ray emitters, positron annihilation CT systems, magnetic resonance, ultrasound computed tomographic systems, CT simulators used solely for treatment planning purposes in conjunction with an MRT unit, and non-diagnostic, intra-operative guidance tomographic units.

Research CT Scanners

The Department received testimony from one (1) organization that recommends that CT standards allow applicants to acquire a CT scanner used exclusively for research. The organization believes that CT should be more consistent with MRI and PET standards in allowing research scanners.

Section 8 of the MRI standards lists the requirements to establish a dedicated research MRI unit.

Section 10 of the PET standards lists the approval requirements for applicants proposing a dedicated fixed research PET scanner.

Currently, the CT standards only allow for applicants proposing to utilize a CT scanner for the sole purpose of performing dental CT examinations exclusively for research. An applicant proposing a dedicated fixed research CT scanner must meet the same requirement as all other CT scanners.

Replacement and Relocation of CT Scanners

The Department received testimony from one (1) organization that feels that the replacement and relocation language in the CT standards are restrictive and may not be meeting the specific needs of the applicant. The organization feels that the Department should investigate a "system view" of imaging asset deployment.

Sections 7 and 8 of the standards list the requirements of replacing both an existing CT scanner as well as an existing dental CT scanner.

Sections 9 and 10 of the standards list the requirements of relocating an existing CT scanner as well as an existing dental CT scanner.

Escalating Utilization Volumes

The Department received testimony from one (1) organization that feels there has been a proliferation of numbers, types and locations of CT units with escalating utilization volumes.

According to survey data staff found the number of fixed CT units for the following years:

2005	2006	2007	2008
242	291	289	363

(It should be noted that these figures are not a true comparison of each year due to changes in the survey model and reporting values.)

Portable Point of Care CT Scanners

The Department received testimony from one (1) organization requesting that there be a permanent allowance for portable point of care CT scanners as an alternative to fixed CT scanners.

"The CereTom is a portable eight slice CT scanner capable of performing NeCT, Xenon Perfusion, and CT Angiography studies. It is used in ICU's, ER's, OR's, and NICU's, and interventional suites in over 100 of the top medical centers in the US and worldwide." This is the portable point of care scanner that the

organization is the manufacturer of and is requesting that the CON standards allow for.

Staff reviewed the Internet Journal of Emerging Medical technologies website and found that CereTom is the world's first cordless and wireless head and neck mobile CT. The equipment can be used at the bedside, in the ER, ICU and private offices. Its primary use is as a head and neck CT scanner because of the size.

Additional staff review of the NeuroLogica website, the manufacturer of the CereTom, found that this scanner provides rapid scanning and immediate viewing of the images for physicians.

The CT scanner standards effective June 20, 2008 allowed for a pilot program for approval of hospital-based portable CT scanners. These standards list the requirements for approval for initiation, expansion, replacement, and acquisition of hospital-based CT scanners. The pilot program approved by the CON Commission expired on October 1, 2008.

The Department received applications from 4 (four) hospitals for initiation of a hospital-based CT scanner. Those four hospitals were approved to initiate a hospital-based portable CT scanner. Since approval one hospital has initiated their portable CT scanner and one hospital has chosen to not implement.

MDCH Staff Recommendations

MDCH recommends that the Commission consider the necessity of addressing the identified issues, and further recommends that the issues to be addressed be referred to the Department for additional review. While the subject of CT regulation and standards has been extensively debated for the past several years, there are still strong differences of opinion on many issues. During this review cycle several suggestions for modifying the standards have been received which the Commission may wish to have explored further.

The CT standards have been modified four times since 2004. More specifically they were revised in June 2004, December 2006, and twice in 2008.

MICHIGAN DENTAL ASSOCIATION
Michigan's Oral Health Authority Dedicated to the Public and the Profession

January 27, 2010

Mr. Edward B. Goldman, JD
Chairman
Certificate of Need Commission
Michigan Department of Community Health
201 Townsend, 7th Floor
Lansing, Michigan 48913

Re: CON Standards for CT Services

Dear Chairman Goldman,

As you review the CON Standards for CT services this year, I wanted to remind you that the MDA continues to request that the CON Commission exempt Dental CT from these standards. If you recall, we have worked with workgroups and SACs over the past 4 years to either exempt or at least improve the dental CT provisions within the standards but to no reasonable conclusion. Most recently, we worked with MDCH in a workgroup setting back in 2008 where it seemed some progress was being made. However, those workgroup meetings stopped suddenly in October 2008. At the December 2008 Commission meeting the Department indicated they would provide a written report of the Workgroups progress at a later date, but as far as we are aware, that has never happened. We feel that Dentists have been pulled into CON regulations for the wrong reasons and do not feel this issue has been resolved.

There are many important reasons why Dental CT should not be regulated by CON and should instead be exempted. First, the cost of a Dental CT is relatively inexpensive when compared to medical CT and even traditional dental imaging, both in the equipment itself and in the cost of the scan. Dental CT units cost an average of $135,795 based on CONs filed in 2009, whereas Medical CT units average $1,239,800. Regarding the cost to payers, Dental CTs are charged at a rate of $125 - $450, whereas Medical CT are reimbursed at a rate of $535 - $1,042. In fact, promoting the use of Dental CT will actually decrease the overall cost of dental imaging as traditional imaging typically costs a total of $540 for equivalent uses.

In addition to the cost aspects, the quality improvements to dentistry through the use of Dental CT are important. Not only are the images for dentistry better with a dental CT, but the quality of patient care is greatly improved in many ways. Complications from oral surgery are greatly reduced when the surgery is planned using the 3D imaging provided by Dental CT. Planning for orthodontics using 3D imaging provided by Dental CT allows patients to be treated more efficiently and effectively. Most importantly, radiation exposure to patients is greatly reduced. A dental CT scan exposes the patient to more than 80% less radiation than a medical CT. Although a Dental CT and Panoramic X-ray are similar in radiation exposure, because a panoramic x-ray is usually performed in conjunction with at least cephelometric x-rays, the Dental CT still comes in with lower radiation exposure than the traditional images.

By continuing to regulate Dental CT within the CON system, we are creating barriers to dentists implementing this new imaging system and making this technology available to the citizens of

Michigan. The current standards do not allow for orthodontic indications to either count toward initiating, or even to utilize, the dental CT once CON approved. The CON process itself is not inexpensive between application fees, consultant fees, and the time and energy that is necessary to prepare the application and usher it through the review cycle. Dentists do not have planning departments that are used for preparing CON applications and if you don't know the practical realities of filing a CON application, you should try it sometime.

And as you can see by the fact that we have been working on this for over 4 years now, CON does not respond fast enough to keep up with emerging uses of this technology in the dental field. Orthodontics is the perfect example of this. All orthodontists being trained at University of Detroit Mercy are trained with a Dental CT scanner and when they graduate and try to set up practice they expect to utilize Dental CT in their practice. By continuing to regulate Dental CT and by refusing to add orthodontics to the list of approved Dental CT indicators, you leave these new graduates with no options for setting up a practice in Michigan utilizing the technology they were trained with.

The Radiation Safety Section of MDCH has put forth proposed changes to their rules which would exempt Dental CT from their CT rules. CON should also recognize the significant differences between Dental CT and medical CT and should follow suit by also exempting Dental CT from the CT standards.

I appreciate the opportunity to refresh your memory on this very important issue and hope that you will incorporate our concerns into your plans for addressing potential changes to the standards this year.

Respectfully,

Caroline M. Ruddell

Caroline Ruddell
Director of Legislative and Insurance Advocacy

MDCH Recommendations for CON Standards Scheduled for 2010 Review

Nursing Home and Hospital Long-Term-Care Unit Beds (NH) Standards (Please refer to the attached MDCH staff analysis for additional details.)			
Should the covered service continue to be regulated?	Not applicable, as a licensed Nursing Home is a licensed health facility, not a covered clinical service. Therefore, deregulation is not an option.		Continued regulation of this licensed health facility.
All Identified Issues	**Issues Recommended as Requiring Review**	**Recommended Course of Action to Review Issues**	**Other/Comments**
1. Modify the Comparative Review Criteria?	Yes.	The Department is reviewing the criteria and will recommend possible improvements.	
2. Modify the Relocation criteria in Section 7?	Yes.	No action at this time.	
3. Modify the High Occupancy Criteria in Section 6?	No.	No action at this time.	
4. Increase the number of Special Pool Hospice Beds?	No.	No action at this time.	
5. Department recommended technical/format changes to the Standards.	Yes.	The Department will draft the technical changes.	

Recommendation:

The Department recommends that the Commission take no action on the requests to modify the relocation and high occupancy criteria and the request to increase the number of Special Population Group for Hospice Care beds. The Department is reviewing the comparative review criteria for possible improvements. A report and recommendation on the comparative review criteria and the technical changes will be presented to the Commission at a future meeting.

Health Policy Section
Revised 01/20/10
Andrea L. Moore

MDCH Staff Analysis of the Nursing Home and Hospital Long-Term-Care Unit Beds (NH) Standards

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 NH Standards are scheduled for review in calendar year 2010.

Public Hearing Testimony

The Department held a Public Hearing to receive testimony regarding the Standards on October 20, 2009, with written testimony being received for an additional seven (7) days after the hearing. Testimony was received from six (6) organizations and is summarized as follows:

1. Aging Services of Michigan
   - Recommends a SAC be appointed to review the Standards.
   - Recommends that the high occupancy criteria be lowered from 97% to 94%.
   - Recommends that the comparative review criteria be modified to award higher points for facilities with high Medicare patient days or full Medicare certification.
   - Recommends that the Standards discourage or deny requests for facilities with more than 250 beds.
   - Recommends that the Standards deny any requests from a facility that currently has Medicaid "non-available" beds due to low occupancy.

2. Blue Cross/Blue Shield of Michigan and Blue Care Network
   - Supports the positions of the provider organizations and consumer organizations to convene a SAC to review these Standards.

3. HCAM
   - Recommends no modification at this point. Notes that these Standards have only been in place for 16 months and a longer amount of time is necessary to evaluate the major changes that went into effect in 2008.
   - Recommends that if a SAC is appointed, that it be made up of equitable representation from all long term care groups and that the charge be very limited.
   - Notes that the comparative review criteria provides little differentiation between facilities and could be re-evaluated.

4. HCR ManorCare
   - Recommends opening the Standards on a limited basis.
   - Recommends modification to the comparative review criteria, the high occupancy language, and the relocation language in Section 7.
   - Recommends adding criteria which would allow a facility to add 10 beds or 10% of the licensed capacity, every two years.
   - Recommends that a pre-licensure CON certification process be established.

5. Lakeland Health Care
   - Recommends that the Commission add additional beds to the special population group for hospice services. There are not any hospice beds available and Lakeland Health Care is interested in starting a hospice program.

6. Spectrum Health Hospitals
   - Recommends no changes to the Standards at this time. Notes that the current Standards have not been in effect long enough to evaluate the effectiveness of the previous changes.

Regulation of the Covered Service

The NH Standards regulate a licensed health facility, not a covered clinical service. Therefore, deregulation is not an option. Nursing Home Beds are regulated in all of the 37 states that have CON. The Department recommends continued regulation of the licensed health facility.

Comparative Review Criteria in Section 10

The Department received recommendations from three (3) organizations to evaluate the comparative review criteria. An organization noted that the current criteria is not as effective as it could be in providing the differencing in the facilities. The organizations recommend many comparative review criteria options. The Department agrees that the criteria could be more definitive. The Department is reviewing the current criteria and will provide the Commission with any recommend improvements at a future meeting.

Relocation Criteria in Section 7

The Department received a recommendation to modify the relocation criteria in Section 7 to eliminate the criteria which restrictions the applicant to only being able to move 50% of the beds for licensed nursing home beds to another facility. The criteria took effect on June 2, 2008. Thus, sufficient time has not transpired to evaluate the effectiveness of the criteria. The Department recommends no action at this time, but will continue to monitor the criteria for impact and effectiveness.

High Occupancy Criteria in Section 6(1)(d)(ii)

The Department received recommendations from two (2) organizations to evaluate the high occupancy criteria. In Section 6(1)(d)(ii) allows a facility to obtain up to 20 beds if the facility has had an average occupancy of 97% for 12 months. An organization noted that this criteria is much hard to obtain for facilities with smaller number of beds. The criteria was modified with the Standards that took effect on June 2, 2008. Thus, sufficient time has not transpired to evaluate the effectiveness of the criteria. The Department recommends no action at this time, but will continue to monitor the criteria for impact and effectiveness.

Special Population Group for Hospice Beds

The Department received a recommendation to add additional beds to the special population group for hospice services. Section 3 (1)(a) of the Addendum for Special Population Groups (Addendum) allocated 1,109 additional nursing beds to the following groups: Traumatic Brain Injury (TBI)/Spinal Cord Injury (SCI) Beds (400 beds), behavioral beds (400 beds), hospice beds (130 beds), and ventilator-dependent beds (179 beds). The allocation of these beds went into effect on June 2, 2008.

The Standards address the reallocation of beds from the statewide pool to special populations groups in Section 3(1)(c)(i) – (iii) of the Addendum, which states:

> ***Section 3(1)(c)*** *The number of beds set aside from the total statewide pool established for categories in subsection (1)(a) for a special population group shall be reduced if there has been no CON activity for that special population group during at least 6 consecutive application periods.*
> *(i) The number of beds in a special population group shall be reduced to the total number of beds for which a valid CON has been issued for that special population group.*
> *(ii) The number of beds reduced from a special population group pursuant to this subsection shall revert to the total statewide pool established for categories in subsection (1)(a).*
> *(iii) The Department shall notify the Commission of the date when action to reduce the number of beds set aside for a special population group has become effective and shall identify the number of beds that reverted to the total statewide pool established for categories in subsection (1)(a).*

There have been 5 application periods since the allocation of the beds from the statewide pool to special populations groups. Section 3(1)(c) requires that 6 applications periods with no activity have transpired prior to reducing beds from a special population group and returning them to the statewide pool for reallocation to a different special population group. The current bed need and the activity in each special population group since June 2, 2008 is outlined below:

Special Population Group	TBI/SCI Beds	Behavioral Beds	Hospice Beds	Ventilator Dependent Beds
Bed Pool pursuant to Section 3 (1)(a) of the Addendum	400	400	130	179
Licensed Beds*	0	0	102	0
Dept Inventory*	80	0	118	0
Unmet Bed Need*	320	400	12	179
Most recent application period with CON activity since June 2, 2008	October 2008	October 2009	October 2009	October 2009

*Data from the January 4, 2010 Bed Inventory

Due to activity in all special population groups and that there have only been 5 application periods since the allocation of the beds on June 2, 2008, the Standards dictate that no reallocation can transpire at this time.

Department Technical Changes

The Department recommends technical/editorial modifications to the Standards to update language and revise format. The Department will present proposed language to the Commission at a future meeting.

MDCH Staff Recommendations

The Department recommends that the Commission take no action on the requests to modify the relocation and high occupancy criteria and the request to increase the number of Special Population Group for Hospice Care beds. The Department is reviewing the comparative review criteria for possible improvements. A report and recommendation on the comparative review criteria and the technical changes will be presented at a future meeting.

Testimony on behalf of Aging Services of Michigan to the
Certificate of Need Commission
October 20, 2009

Good morning, my name is David Herbel, and I am President and CEO of Aging Services of Michigan. Aging Services of Michigan represents more than 230 not-for-profit aging service providers statewide. We are ***the only*** Association in Michigan to represent the entire array of programs and services to seniors. Aging Services of Michigan advocates for a long term care system that supports services at all levels of care and settings.

Aging Services of Michigan would like to ask the Certificate of Need Commission to open up the Nursing Home Standards. Additionally, we would ask that a Standards Advisory Committee be populated with true subject matter experts able to address the following issues:

- **High Occupancy**
  Under the current CON standards, to add beds to an existing facility, the facility must show there is a need for additional beds in the planning area under the bed need methodology, unless the high occupancy exception is satisfied. To qualify for additional beds under the high occupancy exception, the applicant must demonstrate an average occupancy rate of a t least 97% for the last 12 quarters of operation.

  Rationale
  The 97% occupancy rate is too high and unachievable. A workgroup suggested an average 94% occupancy rate must be demonstrated for the last 12 months. Hospitals already enjoy such a standard.

- **Comparative Review**
  In contrast to the high number of points awarded for Medicaid participation/ high Medicaid utilization (21 total); only 2 points are awarded for 100% Medicare participation.

  More comparable criteria could be added to increase the points awarded for facilities with high Medicare patient days or full Medicare certification.

  Rationale
  An acute- care hospital is the most costly setting for inpatient care, thus, CON program goals of cost, quality and access are addressed by allocating points to facilities that improve access to high-acuity units for Medicare beneficiaries needing placement for post-hospital skilled nursing rehab.

- **Facility Size**
  When the bed need number changed effective June 1, 2008, numerous CON applications were submitted. In many instances providers submitted CON applications to try to "grab" available beds in an interim strategy by proposing to tack them onto their existing facilities. Add 140 beds to an existing 239 bed facility for a total of 379 beds at that site. It would be helpful to have language in the CON Standards that: (1) would prevent MDCH from accepting a CON application seeking to establish a nursing home with more than 250 beds; and (2) would disfavor very large nursing homes.

  Rationale
  Research suggests that larger facilities provide lower quality of care and quality of life.

- **Medicaid "Non-Available" Bed Plan**
  Applicant would be ineligible to obtain beds from the bed pool for an existing facility or same licensee if it is currently subject to a Medicaid "non-available" bed plan because some of its existing licensed beds are not being used for patient care due to low occupancy.

  Alternatively, or as an additional criterion, an applicant in a comparative review with a Medicaid "non-available" bed plan in the last 3 years would have points deducted.

Additionally, we strongly encourage the commission to appoint a committee that is time limited with a narrow charge. We believe this is the best way to promote positive outcomes.

Aging Services remains committed to inclusion of quality outcomes in both the CON application process as well as the comparative review standards.

Again, thank you for considering Aging Services of Michigan's concerns and suggestions. Please do not hesitate to call me or my Vice President of Government Strategy, Stephanie Shooks, with any questions or concerns.

David Herbel
President and CEO
Aging Services of Michigan
(517) 323-3687

Aging

ONE VOICE ONE MISSION

January 28, 2010

Edward Goldman, Chair
Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Selection
Capitol View Building, 201 Townsend Street
Lansing, MI 48913

Dear Mr. Goldman,

Thank you for the opportunity to provide testimony on behalf of Aging Services of Michigan. Aging Services of Michigan represents more than 230 not-for-profit aging service providers statewide. We are ***the only*** Association in Michigan to represent the entire array of programs and services to seniors. Aging Services of Michigan advocates for a long term care system that supports services at all levels of care and settings. The Certificate of Need Standards applicable to our members is currently up for review under the customary three year process.

To reiterate our October 20, 2009 testimony, Aging Services of Michigan would like to ask the Certificate of Need Commission to open up the Nursing Home Standards. We would ask that a Standards Advisory Committee be populated with true subject matter experts able to address the following issues: High Occupancy, Comparative Review, Facility Size, and Medicaid "Non- Available" bed plan.

Additionally, we strongly encourage the commission to appoint a committee that is time limited with a narrow charge. We believe this is the best way to promote positive outcomes.

Aging Services remains committed to inclusion of quality outcomes in both the CON application process as well as the comparative review standards.

Again, thank you for considering Aging Services of Michigan's concerns and suggestions. Please do not hesitate to call me with any questions or concerns.

David Herbel
President and CEO
Aging Services of Michigan
(517) 323-3687

MDCH Recommendations for CON Standards Scheduled for 2010 Review

Neonatal Intensive Care Services/Beds (NICU) (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.
All Identified Issues	**Issues Recommended as Requiring Review**	**Recommended Course of Action to Review Issues**	**Other/Comments**
1. Evaluate the effects of decrease births and population on NICU bed need levels.	No.	No action on this issue at this time.	
2. Remove the 5-bed cap from the high occupancy criteria in Section 5(2)(c).	No.	No action on this issue at this time.	
3. Department recommended technical/format changes to the Standards.	Yes.	The Department will draft the technical changes.	

Recommendation:

The Department recommends that the Commission take no action on the requests to evaluate the effects of the decrease in births and removing the 5-bed cap in the high occupancy language criteria, based on the lack of utilization of this criteria. The Department will present technical changes to the Standards at a future meeting.

MDCH Staff Analysis of the Neonatal Intensive Care Services/Beds (NICU) Standards

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 NICU Services Standards are scheduled for review in calendar year 2010.

Public Hearing Testimony

The Department held a Public Hearing to receive testimony regarding the Standards on October 20, 2009, 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 and Blue Care Network
   - Recommends a Standard Advisory Committee (SAC) be appointed to review the effects of the decrease in population and births in Michigan to ensure there is not overcapacity.

2. Spectrum Health Hospitals
   - Recommends modification to the expansion criteria in Section 5(2)(c) to eliminate the 5 bed cap.

3. University of Michigan Health Systems
   - Supports the regulation of this service.
   - Recommends modification to the expansion criteria in Section 5(2)(c) to eliminate the 5 bed cap.

Regulation of the Covered Service

A NICU bed, as defined in the Standards, is a licensed hospital bed designated for NICU services. Given that hospital beds are a covered service within CON, then NICU should continue to be a covered clinical service. NICU Services are regulated by 23 of the 37 state that have CON. The Department recommends continued regulation of NICU services.

Bed Need Methodology

The Department received one recommendation to evaluate the effects of decrease population and births in Michigan to ensure there is not overcapacity of NICU beds. The bed need methodology utilizes the annual number of live births per Health Service Area (HSA) with a very low birth weight (VLBW) adjustment factor for infants weighing less than 1,500 grams. A historical overview of the data of live births, VLBW births, and the resulting bed need are in the following table:

Live Births in Michigan and Resulting NICU Bed Need			
Year	**Live Births**	**VLBW Births**	**Resulting Bed Need**
2002	127,455	2,036	576
2004	128,572	2,109	581
2005	125,456	2,085	569
2007	122,940	2,089	553
2008	119,183	2,143	537
Percentage of change between 2002 and 2008	**6.49% Decrease**	**4.99% Increase**	**7.26% Decrease**

Since 2002, there has been a 6.49% decrease in live births, but a 4.99% increase in VLBW births. This has resulted in a 7.26% decrease in the bed need numbers. The following table looks at the current bed need per HSA:

Overview of Current Bed Need per HSA					
HSA	**Licensed Beds***	**Department Inventory***	**Area Bed Need***	**Unmet (Excess) Bed Need***	**2008 Average Occupancy per HSA****
HSA 1	358	373	316	(57)	70.4%
HSA 2	33	33	31	(2)	92.4%
HSA 3	45	45	37	(8)	84.6%
HSA 4	82	82	82	0	56.7%
HSA 5	44	44	36	(8)	69.6%
HSA 6	40	40	34	(6)	84.6%
HSA 7	24	24	11	(13)	50.7%
HSA 8	10	10	6	(4)	79.2%
Statewide Totals	**636**	**651**	**553**	**(98)**	**71.1%**

*Data from the January 4, 2010 Bed Inventory.

**Data from the 2008 Annual Survey Data, a complete copy is attached as Attachment A.

The bed need methodology takes into account and has compensated for the decrease in live births by lowering the bed need. Unfortunately, the Standards do not establish a method for the Department to remove any NICU beds from a facility due to under-utilization. Thus, like other bed standards, the State ends up being over-bedded in NICU during times of lower birth rates. While the State is over-bedded, the Standards keep facilities from opening new NICU programs. The decrease in live births has resulted in the State currently being over-bedded by 98 beds or 17.7%. No new programs would be allowed to open in any HSA. It is recommended that no action be taken on this issue.

High Occupancy Criteria in Section 5(2)(c)

The Department received two recommendations to remove the 5-bed cap from the high occupancy criteria in the Section 5(2)(c) of the Standards. The criteria allows a facility that treats a high volume of transfer patients from another NICU the ability to add five (5) additional NICU designated beds. The Department reviewed the utilization of this criteria over the last several years and found that it has only been utilized by a very small number of facilities. Given the frequency of use of this criteria and the low NICU occupancy rates in 2008, it is recommended that no action be taken on this issue.

Department Technical Changes

The Department recommends technical/editorial modifications to the Standards; including streamlining Section 1, reorganizing the order and numbering of several Sections and minor updates language. The Department will present the technical changes to the Standards at a future meeting.

MDCH Staff Recommendations

The Department recommends that the Commission take no action on the requests to evaluate the effects of the decrease in births and removing the 5-bed cap in the high occupancy language criteria, based on the lack of utilization of this criteria. The Department will present the technical changes to the Standards at a future meeting.

2008 Michigan Certificate of Need Annual Survey
Neonatal Intensive Care Services
Report 030

Facility Number	Facility Name	Sub-Area	Number of Licen. Beds	Licensed Bed Days	Patient Days of Care	Discharges*	Average Daily Census	Occupancy Rate	Length of Stay (Days)
63.0030	WILLIAM BEAUMONT HOSPITAL, ROYAL OAK	1A	38	11,848	11,806	748	32.3	99.6%	15.8
63.0130	PROVIDENCE HOSPITAL AND MEDICAL CENTER	1A	15	5,490	2,991	200	8.2	54.5%	15.0
63.0140	ST. JOSEPH MERCY OAKLAND HOSPITAL	1A	15	5,490	4,975	441	13.6	90.6%	11.3
63.0160	WILLIAM BEAUMONT HOSPITAL, TROY	1A	15	1,575	157	75	0.4	10.0%	2.1
74.0020	PORT HURON HOSPITAL	1G	4	1,464	924	148	2.5	63.1%	6.2
81.0030	ST. JOSEPH MERCY ANN ARBOR HOSPITAL	1H	15	5,490	3,114	991	8.5	56.7%	3.1
81.0060	UNIVERSITY OF MICHIGAN HOSPITALS	1H	40	14,640	12,859	412	35.1	87.8%	31.2
82.0120	OAKWOOD HOSPITAL AND MEDICAL CENTER	1C	30	10,980	8,869	401	24.2	80.8%	22.1
83.0080	CHILDREN'S HOSPITAL OF MICHIGAN	1D	45	16,470	8,953	767	24.5	54.4%	11.7
83.0190	HENRY FORD HOSPITAL	1D	35	12,810	7,695	274	21.0	60.1%	28.1
83.0220	HARPER UNIVERSITY HOSPITAL	1D	36	13,176	6,820	431	18.6	51.8%	15.8
83.0420	ST. JOHN HOSPITAL & MEDICAL CENTER	1D	35	12,810	10,707	468	29.3	83.6%	22.9
83.0450	SINAI-GRACE HOSPITAL	1D	20	7,320	4,334	364	11.8	59.2%	11.9
HSA 1: SOUTHEAST MICHIGAN	13 Facilities		343	119,563	84,204	5,720	230.1	70.4%	14.7
33.0060	EDWARD W SPARROW HOSPITAL	2A	33	12,078	11,159	489	30.5	92.4%	22.8
HSA 2: MID-SOUTHERN	1 Facilities		33	12,078	11,159	489	30.5	92.4%	22.8
39.0020	BRONSON METHODIST HOSPITAL	3A	45	16,470	13,927	614	38.1	84.6%	22.7
HSA 3: SOUTHWEST	1 Facilities		45	16,470	13,927	614	38.1	84.6%	22.7
41.0040	SPECTRUM HEALTH BUTTERWORTH HOSPITAL	4H	67	24,522	14,241	658	38.9	58.1%	21.6
41.0080	SAINT MARY'S HEALTH CARE	4H	15	5,490	2,779	129	7.6	50.6%	21.5
HSA 4: WEST MICHIGAN	2 Facilities		82	30,012	17,020	787	46.5	56.7%	21.6
25.0040	HURLEY MEDICAL CENTER	5B	44	16,104	11,202	734	30.6	69.6%	15.3
HSA 5: GENESEE-LAPEER-SHIAWASSEE	1 Facilities		44	16,104	11,202	734	30.6	69.6%	15.3
73.0061	COVENANT MEDICAL CENTER - HARRISON	6F	40	14,640	12,385	642	33.8	84.6%	19.3
HSA 6: EAST CENTRAL	1 Facilities		40	14,640	12,385	642	33.8	84.6%	19.3
24.0030	NORTHERN MICHIGAN REGIONAL HOSPITAL	7B	12	4,392	619	52	1.7	14.1%	11.9
28.0010	MUNSON MEDICAL CENTER	7F	12	4,392	3,837	284	10.5	87.4%	13.5
HSA 7: NORTHERN LOWER	2 Facilities		24	8,784	4,456	336	12.2	50.7%	13.3
52.0050	MARQUETTE GENERAL HEALTH SYSTEM	8G	10	3,660	2,897	229	7.9	79.2%	12.7
HSA 8: UPPER PENINSULA	1 Facilities		10	3,660	2,897	229	7.9	79.2%	12.7

*If discharges were unavailable, admissions were reported. The data appear as they were reported by the facility and do not necessarily reflect certificate of need approved services.

Data from Section L of the survey.

2008 Michigan Certificate of Need Annual Survey
Neonatal Intensive Care Services
Report 030

Facility Number	Facility Name	Sub-Area	Number of Licen. Beds	Licensed Bed Days	Patient Days of Care	Discharges*	Average Daily Census	Occupancy Rate	Length of Stay (Days)
State Total	**22 Facilities**		**621**	**221,311**	**157,250**	**9,551**	**429.6**	**71.1%**	**16.5**

Licensed bed counts are listed as of December 31, 2008 from the Licensing and Certification Division, Bureau of Health Systems, MDCH. The calculations for licensed bed days account for the adding and delicensing of beds throughout the calendar year based on MDCH records.

*If discharges were unavailable, admissions were reported. The data appear as they were reported by the facility and do not necessarily reflect certificate of need approved services. Data from Section L of the survey.

MDCH Recommendations for CON Standards Scheduled for 2010 Review

Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Standards (Please refer to MDCH staff summary of comments for additional detail - attached)			
Should there be continued regulation of UESWL under CON?	No.		MDCH recommends that the Commission consider deregulating UESWL services.
All Identified Issues	**Issue Recommended for Review?**	**Recommended Course of Action to Review Issues:**	**Other/Comments:**
1. Lower the volume requirement for expansion of service.	No.	None.	This appears to be an exception and would impact only one organization. There is no evidence of statewide implications or impact of the change on a statewide basis.
2. Create a rural adjustment factor.	No.	None.	This appears to be an exception and would impact only one organization. There is no evidence of statewide implications or impact of the change on a statewide basis.
Recommendation: MDCH recommends that the Commission consider deregulating UESWL services. UESWL is a well established and low-cost service and there has been no evidence provided to support concerns regarding either a proliferation of services or an increase in re-treatment numbers.			

MDCH Staff Analysis of the Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Standards

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 UESWL Services Standards are scheduled for review in calendar year 2010.

Public Hearing Testimony

The Department held a Public Hearing to receive testimony regarding the Standards on October 20, 2008, with written testimony being received for an additional seven (7) days after the hearing. Testimony was received from two (2) organizations and is summarized as follows:

1. Ann Stevens, Greater Michigan Lithotripsy:
    - Concerned with the number of cases required under the CON to expand the number of units on a mobile route. They feel the number is excessive and results in insufficient access.
    - Recommend that a volume requirement based on the national experience, as they cite within the letter, be incorporated into the CON standards for expansion of a mobile lithotripsy route.
    - Additionally, they believe that there should be a rural adjustment factor of two (2) applied to rural host sites. This would help to address the rural access issue they see.
2. Jorgen Madesen, United Medical Systems/Great Lakes Lithotripsy:
    - Strongly believes that there should be continued regulation of the UESWL services.

Regulation of Covered Service

The Department did not receive any testimony against the continued regulation of UESWL Services. One (1) organization submitted testimony containing reasons why UESWL should continue to be regulated under CON. The reasons they gave are as follows: if UESWL is deregulated then physicians would have easier access to obtaining their own machine. Abuse would occur as these physicians would have a direct financial incentive to perform more litho procedures. UESWL and other outpatient procedures are typically areas where abuse of this nature can occur. They state that a proliferation of equipment would occur if deregulation took place. Additionally, they state that CON provides an oversight role in UESWL treatments. This role is something that needs to be maintained as there is currently a high level of re-treatments occurring. They believe that this issue needs closer attention, and therefore, deregulating at this time would be a step in the wrong direction.

Michigan is one of 17 states which regulate Lithotripsy Services within CON.

UESWL Survey Data for 2008:

Facility No.	Type	Facility Name:	# Units	# Procedures	# Retreats
82M103	M	Ford & Harper Mobile Lithotripsy	2	1,959	25
33M147	M	Great Lakes Lithotripsy	1	1,236	9
33M023	M	Great Lakes Lithotripsy, LLC	2	2,112	46
33M074	M	Great Lakes Lithotripsy, LLC	1	1,533	8
99M167	M	Greater Michigan Lithotripsy	1	1,060	105
41M165	M	Spectrum Health – Butterworth	1	1,066	125
63M164	M	William Beaumont Hospital	1	1,013	91
TOTAL			**9**	**9,979**	**409**

Volume Requirement for Expansion

The Department received testimony from one (1) organization requesting that the volume requirement for expansion be lowered.

Section 8(1) of the Standards, requires that all of the applicant's existing UESWL units (both fixed and mobile) at the same geographic location as the proposed additional UESWL unit, performed an average of at least 1,800 procedures per UESWL until during the most recent 12-month period for which the Department has verifiable data.

In looking at the 2008 survey data, none of the nine (9) CSCs would meet the current volume requirement for expansion. For the most part, all are doing on average 1,000 procedures a year per unit.

The Department received testimony from one (1) organization that cited that their management company, American Kidney Stone Management, Ltd. (AKSM) reviewed case load to determine typical volume rates for the AKSM mobile lithotripters. The testimony provided the following facts based on what they found out from AKSM: on a nationwide average, a mobile lithotripter performed 600 cases per year. In addition, the minimum number of cases performed on any single mobile lithotripter is 1,200 cases. Lastly, they state that once volume exceeds 1,000 cases per lithotripter, a second mobile unit is added to the mobile route. The testimony goes on to state the reasoning behind this is that after a second lithotripter is added to a route the overall volume increases. A single mobile lithotripter that treats more than 1,000 cases annually is subject to

increased down time for maintenance and is unable to be physically transported in a timely fashion to the dispersed communities. This being their reasoning that a second lithotripter should be added to a route doing 1,000 or more annually treatments.

Staff review of the AKSM website found that approximately 1,500 physicians across the country utilize the AKSM service. Their technicians assist with more than 28,000 ESWL treatments per year. AKSM operates more than 50 fixed-site, mobile and transportable lithotripters (http://aksm.com).

Rural Adjustment Factor

The Department received testimony from one (1) organization requesting that a rural adjustment factor of two (2) be applied for rural host sites currently providing lithotripsy services and those wanting to initiate. Their testimony stated that patients in rural areas have a longer wait time of 2-4 weeks before receiving needed lithotripsy services. This wait time is due to the fact that the mobile units visit less frequently due to the smaller populations. If patients have to wait a longer period of time before the lithotripsy machine becomes available, then the urologist may choose to seek a temporary fix of inserting a stent until a machine becomes available. Additionally, the testimony goes on to state that the urologist may decide on performing a more invasive procedure on the patient which then poses greater risk.

MDCH Staff Recommendations

MDCH recommends that the Commission consider deregulating UESWL services. UESWL is a well established and low-cost service and there has been no evidence provided to support concerns regarding either a proliferation of services or an increase in re-treatment numbers.

Testimony Re: UESWL Services
CON Commission Meeting
January 28, 2010

Good morning/afternoon. I am Jorgen Madsen, the CEO of United Medical Systems, minority owner of Great Lakes Lithotripsy which owns and manages 4 mobile lithotripsy routes in Michigan. Thank you for this opportunity to provide comments regarding the CON Standards for Lithotripsy Services.

Great Lakes Lithotripsy strongly supports the current CON standards for this service and believes they are working well to ensure access to high quality lithotripsy services while restraining costs. We strongly oppose the Department's recommendation to deregulate this service for many reasons.

These standards may be the perfect example of CON at its finest. The current standards have moved Lithotripsy from a very expensive, fixed unit system, to a low-cost mobile system. By encouraging fixed units to be converted to mobile, these standards have increased access exponentially while keeping costs low. In fact, in 1998 there were 5 fixed lithotripsy sites and 9 mobile lithotripsy host sites, providing access at only 14 sites total across the entire state. 12 years later there are now 9 mobile lithotripsy routes with 11 lithotripsy units total, providing service to 70 host sites in the State; 5 times as many access points than under the previous system but with only twice as many lithotripsy units. Because lithotripsy is a relatively low volume procedure at any single facility, this system has created efficiencies by allowing multiple facilities to utilize the same equipment.

The CON standards provide assurance that facilities providing this service have the necessary equipment and support services to ensure patient safety. These provisions have prevented proliferation of lithotripsy units into physician offices where those necessary support services do not exist. Although lithotripsy is a non-invasive procedure, it is traumatic for the kidney and the patient must be followed carefully to ensure there is no renal bleeding or developing hematomas, which are known complications of the procedure. It is important that these patients are treated in an appropriate facility. It is also vitally important that the physician performing the procedure be properly trained and credentialed, all requirements of the current CON standards.

Patient demand is being met under the current system in a very timely and efficient manner. The current rules allow for the addition of lithotripsy units when demand exceeds capacity, providing for a reasonable expansion of services. Some have recently argued that the expansion criteria are too restrictive and that it is impossible to meet the volume qualifications. We would disagree. In fact, we have qualified under the current rules for expansion of 2 of our 4 routes already, and will be qualifying to expand a third route sometime this year. The rules are reasonable and fair.

The CON staff are recommending deregulation under the assumption that it will not result in proliferation of services, but have provided no support for this assumption. In years past, this Commission has been approached by physicians wishing to provide this service in their offices with their own lithotripsy units. Why would we assume that they would not proceed with their plans once the CON system is no longer in place to ensure this procedure is performed in the most appropriate setting?

In closing, we strongly encourage the continued regulation of lithotripsy services under the current CON standards. The current rules are effective in upholding the 3 tenants of CON – Cost, Quality, and Access. As pointed out by Department staff in their recommendation, there were no public comments advocating for deregulation of this service. Why change something that works so well? I am happy to answer any questions you may have.

Request to Advance the Reviews of the Open Heart Surgery and Cardiac Catheterization Standards

CON Commission Meeting
January 28, 2010

Coalition of Health Systems

MetroHealth

TRINITY HEALTH
Novi, Michigan

BOTSFORD
HOSPITAL

Henry Ford
HEALTH SYSTEM

SAINT MARY'S
HEALTH CARE

MERCY
HEALTH PARTNERS

GARDEN CITY
HOSPITAL

DMC
DETROIT MEDICAL CENTER

HURLEY
MEDICAL CENTER

ST. MARY MERCY LIVONIA
SAINT JOSEPH MERCY HEALTH SYSTEM

Cheryl Miller - Testimony

- Director, Health Networks – Trinity Health, Novi MI,
- Introduction of Coalition member hospitals, health systems who prepared the document and testimony being presented today
  - Botsford Hospital
  - Detroit Medical Center
  - Garden City Hospital
  - Henry Ford Health System
  - Hurley Medical Center
  - Metropolitan Health
  - Trinity Health
- Overview of efforts to date with CON Commission, MDCH leadership
- Request: Advance the review of the Cardiac Cath and OHS standards to 2010 instead of 2011; please consider this matter at January 28th Commission Work Plan meeting
- Testimony today will focus on:
  - Why now? What's the urgency?
  - How these findings fit into 3 tenets of CON: Cost, Quality, Access
- Health care is in transition, shifts are already being seen
  - Pay for performance in lieu of fee for service
  - "Build it and they will come" to patient- centered medical homes
  - Variation in care to standardized evidence-based practices

Thank you for the opportunity to revisit this critical issue

- Represents hospital systems across the State
- Objectives of today's testimony
  - Highlight the issues supporting the acceleration of the review of the Cardiac Cath and Open Heart Standards
  - Request inclusion on January 28th agenda for Commission Work Plan meeting

In response to previous discussions with the Commission and MDCH leadership……

- Why the urgency to review these standards in 2010 instead of 2011 as scheduled?

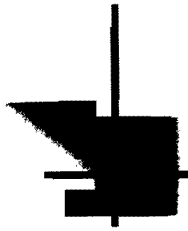
- What has changed that would require an acceleration of the review schedule?

- How do these findings fit into the three tenets of CON?
  - ✓ Access
  - ✓ Quality
  - ✓ Cost

How can the CON program be flexible during the current health care transition?

- **Current reality:**
  - Fee for service (the more we do, the more we get paid)
  - Rewarded for high-tech
  - Specialty focus
  - "Build it and they will come" (brick and mortar)
  - Low accountability for outcomes
  - Extreme variation in care delivery

- **New reality:**
  - Pay for performance (at risk for managing cost, managing chronic conditions, and health outcomes)
  - Patient-centered medical homes
  - Primary care focus
  - Distributed model of care
  - Information-driven
  - Standardization to evidence-based practices



Shifts are already occurring

- **Example: Michigan Blue Cross/Blue Shield's Physician Group Incentive Program (PGIP)**
  - Primary care and select specialty physicians on risk/reward programs for:
    - Patient-centered medical home behavior (open access, patient navigators, disease registries, e-prescribing, continuous improvement initiatives, etc.)
    - Patient satisfaction
      Patient outcomes (e.g., chronic disease management)
    - Now includes gastro, ortho, rad oncology
  - Results:
    - 23% lower inpatient cost PMPM*, 20% lower admissions/1,000
    - 7% lower readmission cost PMPM*
    - 52% lower self-referral rate for low-tech imaging

* Per Member Per Month

Other Important Considerations

- A recent informal NEWTAC meeting included discussion of a new procedure - percutaneous insertion of cardiac valves; concerns were expressed that current standards do not include this new clinical practice.
  - NEWTAC chairman, Dr. Marc Keshishian, doesn't seem interested in waiting until 2011 to review this issue. If a SAC is to be formed to look at this specific matter, a full evaluation of all issues might as well be done.

- The tentative schedule for the review of standards is even more onerous in 2011 than 2010 so it may be wise to move up the OHS and Cardiac Cath reviews to prevent an overload in 2011:

2010	2011
Air Ambulance	Cardiac Cath & OHS
CT	Hospital Beds
Lithotripsy	MRT
NICU	PET
Nursing Homes	Surgical Services

- Consider combining the review of the Cardiac Catheterization and Open Heart Surgery standards into a single Standard Advisory Committee (SAC).

Other Important Considerations (con't)

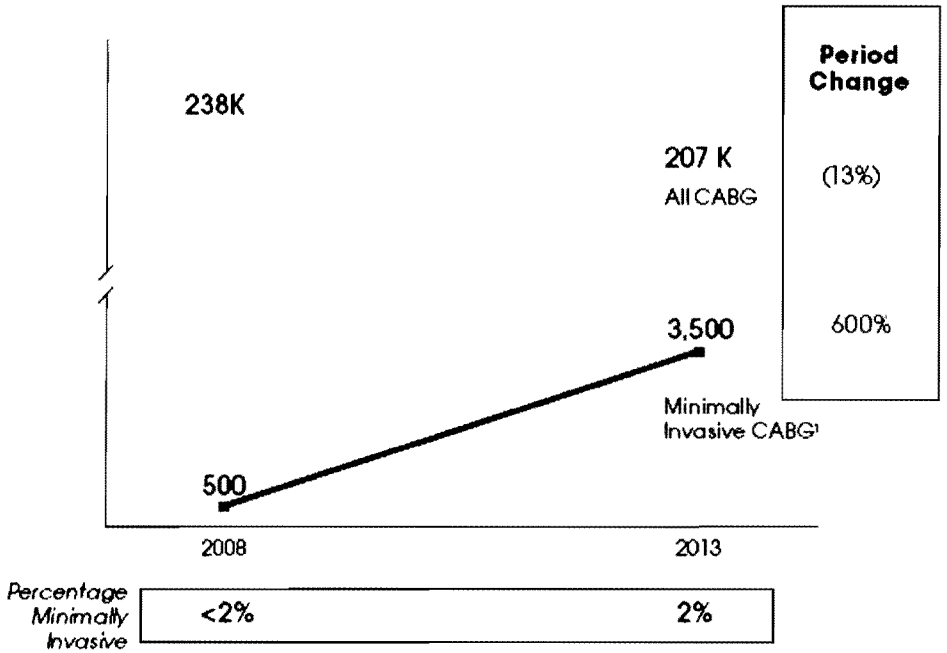
- May help address OHS compliance issues as several of the current programs are having difficulty meeting and/or maintaining required volume levels/thresholds. If OHS was de-linked from therapeutic procedures, some providers might be willing to discontinue their OHS programs. This could lead to fewer OHS programs overall and higher volumes at remaining programs, while at the same time maintaining access to therapeutic procedures.

- Concerning OHS in the Grand Rapids market, the ratio of programs to population is a commonly used measure to determine whether access is sufficient.
  - Nationally: 1 OHS program: 280,964 population
  - Michigan: 1 OHS program: 321,889 population
  - Kent Co.: 1 OHS program: 599,524 population
  - Greater West Michigan region: 1 OHS program: 1,179,394 population

Demand for CABG is projected to continue to decline……

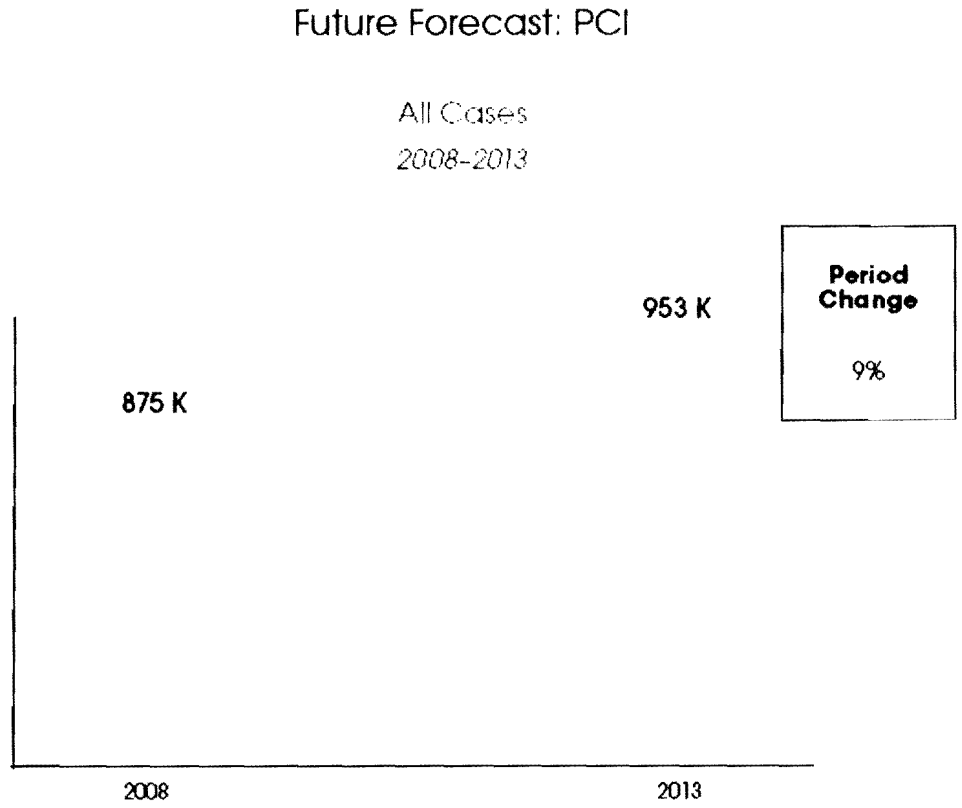
Future Forecast: Minimally Invasive CABG

All Cases, 2008-2013



Source: Best Practice Profile, Cardiovascular Roundtable, Advisory Board April 15, 2009

While the demand for PCI is projected to increase

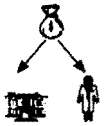


Source: Cardiovascular Roundtable, Advisory Board; July 31, 2009

Cardiovascular bundled payment pilots already in process

New Bundled Payment Demo Underway

Reimbursing for an Acute Care Episode



Bundled Payment

- Combined Parts A/B payment provided to PHO[1]
- Bundled payment for inpatient stay only; potential to expand to post-discharge treatment after one year
- Distribute payment according to pre-determined methodology

Selected Inpatient Procedures

- 28 cardiac procedures including CABG, valves, defibrillator implants, pacemakers, PCI
- Nine orthopedic procedures
- High-volume, easily defined, associated quality measures

Specific Criteria

- Must establish PHO, meet minimum historical volume and quality thresholds
- Must maintain quality; monitoring incorporates 30-day readmission and mortality rates, CABG revision within six months

Additional Payouts

- Optional gainsharing with physicians for quality, cost, efficiency improvements not to exceed 25 percent of normal pay
- Rebate up to 50 percent of Medicare savings to beneficiaries' annual premium

Source: Health Care Policy Horizon Scan, Advisory Board; July 29, 2009

Susan Heck - Testimony

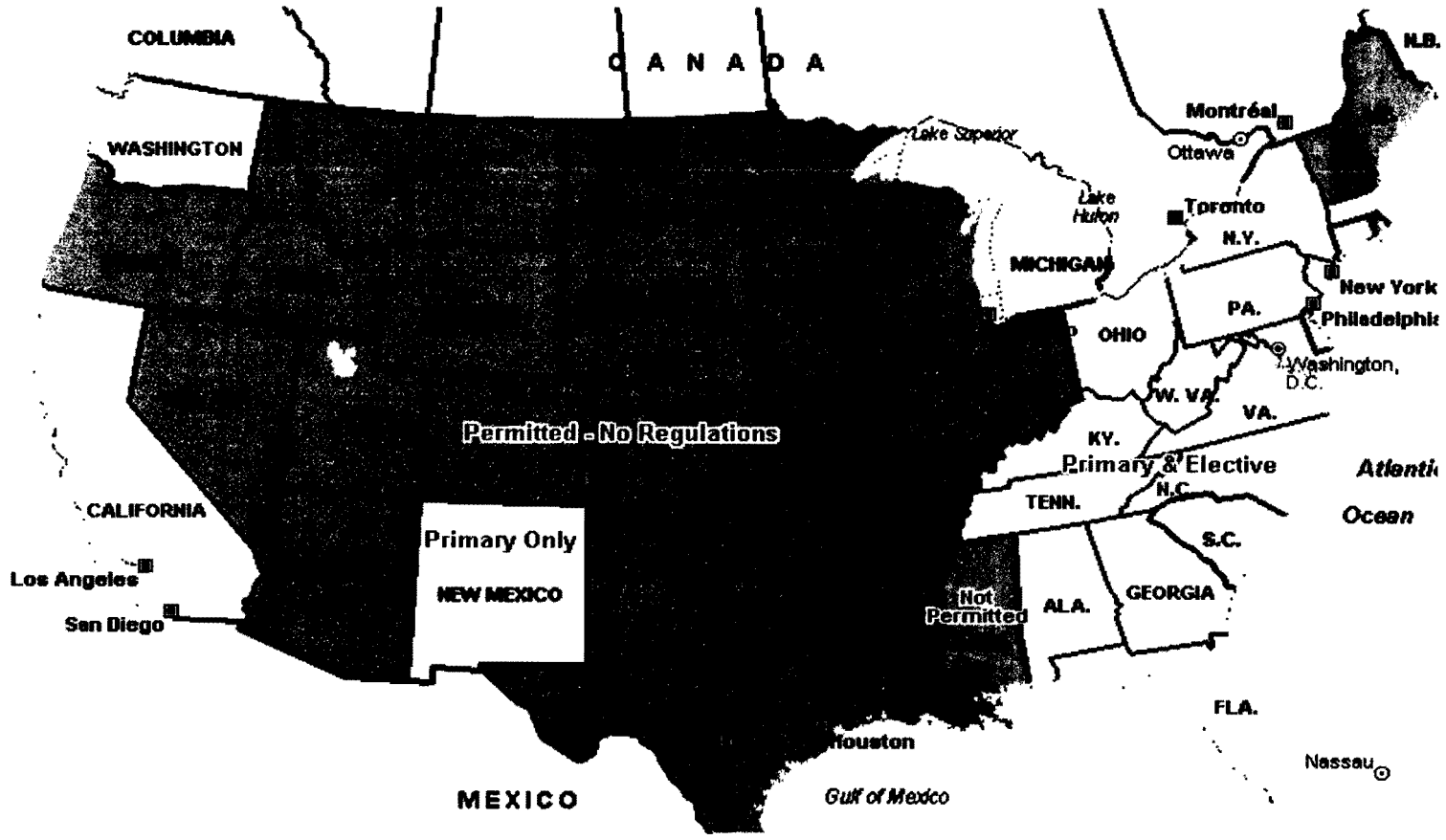
- Susan Heck, Senior Vice President, Corazon, Inc.
- Corazon is a national consulting firm that specializes in cardiac, vascular & neuroscience service development
- Overview of the national regulatory climate related to elective PCI –clinical practice outpacing ACC guidelines
  - Only 4 states do not allow Primary or Elective PCI
  - Only 5 states including Michigan restrict to Primary only
  - 23 have no regulations governing practice
  - 16 states allow Primary and Elective with only 7 of 16 requiring study or trial participation
- A review of the costs to payors for diagnostic cath & elective PCI being performed in staged settings:
  - The net difference between DX cath and Elective PCI in same care setting vs. a staged procedure is approximately $7,300 per case based on a Medicare rate
  - Duplicate testing and redundant costs for dye, catheters, trays
  - Increase length of stay
  - Ambulance transfer fees average $400 per case
  - Given the groups estimate of about 1000 procedures— currently **paying over $7.3 million for less than standard care**

More than 500 centers in U.S. offer PCI without Surgery on Site (SOS) 39 States Allow Elective PCI with varying requirements

RECENT REGULATORY CHANGES

- **California**
  - Allows primary PCI, in Jan '09 bill passed for a pilot to allow 6 hospitals to add elective PCI.
- **Florida**
  - In Jan '09 moved from CON to a 2-level licensure of adult cardiovascular services; Level 1 permits community hospitals meeting specific criteria to offer elective & emergent PCI services, Level 2 facilities provide open heart services.
- **Georgia**
  - In 2005, permitted 10 hospitals to participate in a national clinical trial to allow community hospitals to provide elective & emergent PCI without SOS. In July of '09 16 additional hospitals were granted approval to do primary & elective **without** participation in the C-PORT trial.
- **New York**
  - Engaged in project to allow 10 facilities to perform primary PCI. Regulatory changes signed in Nov of 09 that will allow elective PCI & prohibit the addition of diagnostic only labs.
- **Pennsylvania**
  - Beginning in 2001, 10 programs granted exceptions to pilot to provision of both primary and elective PCI without SOS. In '09 approved 5 new programs if they qualify to participate in the C-PORT trial.
- **West Virginia**
  - In August '08, implemented 3 tiers of service: Tier 1 --must demonstrate a minimum diagnostic cath volume threshold; after 1 year of diagnostic caths, can apply to offer primary PCI under Tier 2. Hospitals that offer primary PCI for at least 2 years may apply to offer elective PCI under Tier 3.

PCI Regulations – State by State



- Not permitted
- Primary only
- Primary & Elective
- Permitted, not regulated

Provided by Corazon, Inc
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Cost

- Failure to allow elective PCI without SOS (surgery on site) means:
  - Increase health care costs associated with the additional expenses of transportation
  - Duplicate testing as patients move from one acute care facility to another
  - Increase in overall length of stay (LOS) incumbent in the staged care process

Payor Cost Avoidance Scenario

Sample based on Medicare

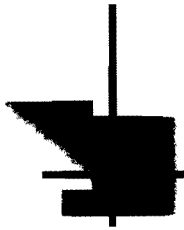
Medicare Costs	Hospital Component	Physician Component (Pro-fee)	Transport Component	Total
DX Cath and Elective PCI in the same setting of Care	$ 11,452	$ 1,108	$ -	$ 12,560
DX cath with a Transfer to another facility for Elective PCI	$ 18,193	$ 1,282	$ 386	$ 19,861
Difference	**$ 6,742**	**$ 174**	**$ 386**	**$ 7,302**

Sample Cost Avoidance	
Sample PCI Case Volume	1,000
Payor Cost Differential	$ 7,302
Total Cost Avoidance	**$ 7,302,000**

- Hospital component for PCI based on CMS split of case volume across DRGs 246-251
- Physician Pro-fee for dx cath based on CMS left heart cath & PCI blended payment rate based on 1.4 stents/case
- Transport based on Michigan ground rates + 10 miles & a blend of Advanced Life Support levels

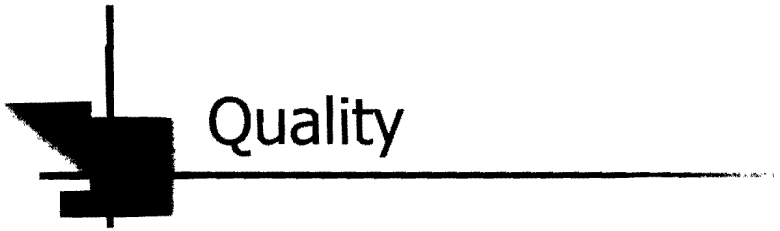
Dr. Jaggi - Testimony

- Mike Jaggi, D.O. –Chief Medical Officer and Director of Emergency Medicine, Hurley Medical Center, Flint, Michigan
- American College of Cardiology (ACC)
  - Acute dissection related to all PCI >1% --actually **0.2%**
  - Practice outpacing ACC's **very conservative position** in their guidelines
  - ACC lead by **academic cardiologists** with vested interest in driving procedures to tertiary hubs
  - National (including ACC's own database) & international data points to safety in new practice
- Changing clinical practice is based on:
  - Technology advances—Improved catheters, wires and stents
  - Growing expertise of cardiologists to manage complications
  - Even tertiary centers no longer hold ORs open or keep staff on stand-by
- Practice of "coupling" diagnostic and PCI procedures in the same care setting is supported by quality and cost outcomes. When programs cannot provide elective PCI:
  - Greater dye, radiation, infection and bleeding complication exposure
  - Disconnect from their medical home
  - Change access to care for the economically disadvantaged populations



Access

- Changing clinical practice supports the"coupling" of diagnostic cath and PCI. Patients are forced to be transferred away from their medical home – which is the complete opposite approach of the current health care and payment reform efforts.
- Even highly regulated states such as New York are changing regulations to allow primary and elective PCI at centers without on-site surgery.
  - Further support to the changing clinical standards related to the coupling of diagnostic and interventional procedures, New York's new regulations prohibit the addition of any new diagnostic only cath labs.



Quality

- Current practice "couples" diagnostic caths with coronary intervention. Given prohibition to do elective caths without SOS (surgery on site), patients in Michigan experience:
  - Exposure to increased amount of blood thinners and increased x-ray dose;
  - Multiple invasive punctures which can lead to peripheral complications and increased chance of infections;
  - A disconnect from their medical home as their medical record and PCPs do not easily cross hospital boundaries at this time;
  - Dissatisfaction with transfer as the patient and family must navigate unfamiliar settings and meet new physicians.
  - Duplicate testing
  - Increased length of stay (LOS) due to transfer

Quality

- Senior author on the study, **Dr Ralph G Brindis** (Northern California Kaiser Permanente, San Francisco, CA), told **heart*wire*** that while there is now an important randomized clinical trial under way, known as **C-PORT Elective**, looking at the feasibility and outcomes of performing elective "off-site" PCI (angioplasty without on-site surgical backup), these new data, culled from the **National Cardiovascular Data Registry** (NCDR), may be persuasive enough to convince guideline-writing groups to reassess some of their advice.
  Source: *http://www.theheart.org/article/981347.do*

- A study in the June 30th issue of the Journal of the American College of Cardiology (JACC) showed patients who received elective percutaneous coronary intervention (PCI, aka angioplasty) at **hospitals without on-site cardiac surgery had no difference in mortality compared with patients receiving the same procedure at hospitals with surgical backup on site**. Some recent media reports have focused on the topic of performing elective PCI at hospitals where no cardiac surgery is performed to 'back up' the procedure should a complication arise. This new study provides additional information suggesting this can be done safely if such programs carefully monitor their results and follow rules about which patients are appropriate for PCI in facilities without on-site surgical backup.
  Sources: *http://www.seconds-count.org/Details.aspx?PAGE_ID=503;*
  http://www.theheart.org/article/981347.do

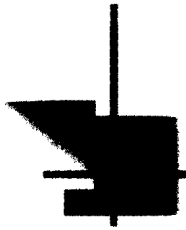
Quality (con't)

- SCAI* Statement On Percutaneous Coronary Intervention (PCI) In Facilities Without On-Site Cardiac Surgery (http://www.seconds-count.org/Details.aspx?PAGE_ID=503)
  - "The ability to perform PCI in community hospitals often translates into an overall improved level of cardiovascular care, enabling the hospital to recruit the most skilled health care providers and offer overall better care to the people they serve."
  - "Advances resulting from the development of stents and the effectiveness of PCI in treating heart attacks, as well as the success of door-to-balloon time programs have led to a decrease in the need for open-heart surgery in patients with blocked arteries. Therefore, cardiac surgery is available at fewer hospitals than in the past."

- The American College of Cardiology's own database (ACC-NCDR) supports that **primary and elective interventions can be performed as safely at programs without open heart surgery on site**. Actual clinical practice evident in their own database supports the fact that practice is outpacing the ACC's endorsement.

- "Optimal outcomes with PCI have been observed at community hospitals without on-site cardiac surgical programs with application of a prospective, standardized quality assurance protocol. The in-hospital mortality rate at Immanuel St. Joseph's Hospital and Franciscan Skemp Healthcare was comparable to that at Saint Mary's Hospital for both elective (0.3%, 0.1%, 0.4%; P=.24) and nonelective PCI (2.6%, 2.4%, 3.1%; P=.49). No patient undergoing elective PCI required transfer for emergency cardiac surgery." (http://www.mayoclinicproceedings.com/content/84/6/501.abstract)

* Society for Cardiovascular Angiography and Interventions



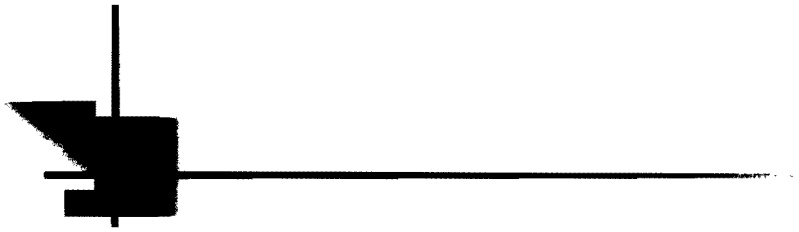
Request from the Coalition

- Please include our request, specifically *the acceleration of the review of both the cardiac cath and OHS standards by one year from 2011 to 2010*, at the January 28th CON Commission Work Plan meeting.

- Consider combining the review of the Cardiac Catheterization and Open Heart Surgery standards into a single Standard Advisory Committee (SAC).

Single SAC for Cardiac Cath and Open Heart Surgery

- Standards are closely tied together and actually overlap in some instances. Making changes in one set of standards will affect the other standards and may warrant changes in them.
- The issue of percutaneous insertion of cardiac valves is a prime example of the two sets of standards overlapping. Although the procedure likely technically meets the definition of cardiac catheterization, it replaces an open heart surgery and likely should only be performed in the most experienced of open heart surgery facilities. Will likely have to address the procedure in both sets of standards and will require consistency.
- Addressing updates and changes to these standards in two separate SACs would require a great deal of communication between the two committees in order to avoid unintended loopholes or conflicting rules. Ensuring appropriate communication may be difficult without having overlapping membership. Communication between SACs was a struggle in 2007 when these standards were last substantively addressed.
- 2/3 of SAC members must be experts in the field of cardiology. Since this is a finite pool of professionals who have very demanding schedules, populating two separate SACs will be a challenge. Adding to that a need to find members willing to attend twice as many meetings (to achieve that overlapping membership) over a 6 month time frame would only multiply the challenge.
- Addressing both the Cardiac Cath and Open Heart Surgery standards in one SAC will ensure consistency between changes in both sets of standards and will eliminate challenges in communication between two separate SACs.
- A single SAC will require half as many meetings for the Department to staff, which utilizes MDCH resources in a more efficient manner, especially at a time when State resources are so limited.
- Although the SAC will be charged with a larger workload than most SACs, taking advantage of opportunities to use workgroups prior to the SAC beginning its work to pull together data and pertinent information, a single SAC should be able to complete its tasks within the 6 month timeframe allowed.




THANK YOU

Attachment K

THE MICHIGAN HEALTH MINISTRIES OF ASCENSION HEALTH

Advocacy Office:

328 West Ottawa Street
Lansing, MI 48933-1587

Phone: 517.482.1422
Fax: 517.374.1326

Health Ministries of Ascension Health Michigan
Testimony to the CON Commission
January 28, 2010
Open Heart Surgery & Cardiac Catheterization Standards Review
Acceleration to the 2010 Work Plan

I am Sean Gehle and am here today representing the hospitals of Ascension Health Michigan. I am here to address the request by certain parties to accelerate the review of Open Heart Surgery/Cardiac Catheterization (OHS/CC) standards from 2011 to 2010.

We do not feel there are sufficient grounds to warrant an accelerated review. The party's presentation at the December Commission meeting while impassioned has not provided demonstrable new rationale from the previous arguments in 2009 in the areas of cost, quality and access to merit an accelerated review. There are significant and important standards on the regularly scheduled work plan that do merit the Commission's attention in 2010.

However, I'd like to briefly address the specifics of cost, quality and access that should define whether there is materiality to support an accelerated review.

Cost:
The cost argument articulated in December suggested increased cost under the present CON standards. This is due to transportation costs, duplicate testing, and increased length of stay of a staged care process. The relatively small numbers of patients requiring the staged care process does not offset the substantial increased costs to the citizens of Michigan by creating additional percutaneous coronary intervention (PCI) programs throughout the State. Per Dr. Winslow, Associate Vice President at Sg2, a national health care forecasting firm, the number of patients requiring inpatient and outpatient intervention are not likely to increase. Thus, an increase in the number of programs with stable market volume will only lead to increased societal costs.

Quality:
Regarding quality and safety of performing elective PCI without on-site surgical back up; the fact is that the clinical policy positions of the American College of Cardiology (ACC), the American Heart Association (AHA), and the Society for Cardiovascular Angiography and Interventions (SCAI) have not changed. All three organizations continue to consider PCI without on-site surgical backup as a Class III Indication, the most serious; meaning "not recommended as being useful or effective; may be harmful".

SCAI developed quality guidelines in 2007 for those hospitals venturing into PCI without on-site surgical back up. The SCAI, in furnishing these stringent guidelines for hospitals performing PCI without surgical backup, clarified their position in a 2007 heartwire article (quoting Dr Gregory Dehmer, SCAI President):

"We certainly support the 2005 guideline update. I specifically would want nobody to think that our putting this document out at the present time in any way, shape, or form either detracts or is meant to contradict the guidelines." He further insisted in an Internal Medicine News 2007 article that the SCAI was "not in any way promoting PCI without surgical backup".

It is clear that the clinical policy organizations are in full agreement that PCI should only be performed with on-site surgical backup. SCAI's issuance of their 2007 quality guidelines caused some controversy, and is an indication that the body of science on this topic continues to evolve. There are studies underway but not complete. This in and of itself suggests the Commission await the outcomes of these studies (ie: C-PORT Elective) for a 2011 standards review.

Access:
Regarding access issues; None of the proponents for accelerated review and standards change have demonstrated that access to these services is compromised, that the proponents of change are in markets with poor access, or that these markets do not have existing PCI programs with on-site surgical back-up in close proximity.

However, data is more compelling. In the United States there are 1,176 PCI hospitals. There is one PCI hospital for every 192,878 adults in the US, based on the 2000 Census of 207.5 Million adults.

In Michigan we have 43 PCI hospitals serving an adult population of 7.8 Million, or one PCI hospital for 181,395 adults.

The data demonstrates that Michigan currently provides slightly better access to PCI services than the United States overall.

Conclusion:
On balance, the parties who are recommending an acceleration of the review of the OHS and CC standards with a desire to disengage the two standards have not demonstrated there is sufficient change from a similar request in 2009. Access has not declined, national clinical policy organizations have not changed their policy positions, and societal cost implications are not adequately addressed. We believe it is in the best interest of the citizens of the State of Michigan for the Commission to not accelerate the OHS/CC standards review from 2011 to 2010. However, if the Commission determines a review is necessary, we suggest that this review be delayed to later in the calendar year (perhaps spanning into 2011) to afford the opportunity for studies in progress to be published and inform the review group.

CERTIFICATE OF NEED (CON) COMMISSION BYLAWS

ARTICLE ~~1~~ I - PREAMBLE

The Michigan ~~Certificate of Need~~CON Commission (~~CON~~ Commission) is created in the Michigan Department of Community Health (the ~~department~~Department) and is established ~~pursuant to~~under the Michigan Public Health Code, 1978 P~~.~~A~~.~~ 368, MCL 333.1101, et seq., ~~MSA 14.15 (1101) et seq., ~~as amended ~~by Public Acts 308, 331 and 332 of 1988, and 396 of 1993, which augmented the Public Health Code by the addition of Part 222~~ (the Code) ~~and amended by Public Act 619 of 2002~~. The Bylaws developed by the ~~CON~~ Commission ~~shall~~ remain in effect until ~~otherwise~~ amended as provided for in Article X.

ARTICLE II - DEFINITIONS

Unless defined in these Bylaws, ~~The~~ the terms used in these ~~bylaws~~ Bylaws have the meaning ascribed to them in Parts 201 and 222 of the Code.

ARTICLE III - GENERAL PURPOSE

The duties of the Commission are set forth in Section 22215 of the Code. The ~~CON~~ Commission ~~shall~~ exercise~~s~~ its duties to promote all of the following:

A. The availability and accessibility of quality health services at reasonable cost and with reasonable geographic proximity for all people in the state;

B. Appropriate differential consideration of the health care needs of residents in rural counties in ways that do not compromise the quality and affordability of health care services for those residents; and

C. Consideration of the impact of a proposed restriction on the acquisition of or availability of covered clinical services on the quality, accessibility, and cost of health services in this state.

~~ARTICLE IV - STANDARD ADVISORY COMMITTEES~~

~~If the Commission determines it necessary, it may appoint standard advisory committees to assist in the development of proposed CON review standards in accordance with section 333.22215(1)(l).~~

~~A. The duties of a standard advisory committee shall be developed by the Commission at a regular or special meeting. A standard advisory committee's duties shall be adopted by a majority of the Commission.~~

~~B. The duties of a standard advisory committee shall be set forth in a written charge enumerating the duties delegated to it by the Commission.~~

~~C. The language of the written charge may be adopted by vote of the commission or the Commission may delegate the Chairperson to write the charge, consistent with the action of the Commission.~~

~~D. The members of a standard advisory committee shall be appointed by the chairperson consistent with statutory requirements and the recommendations of the Commission.~~

~~E. The appointment of a standard advisory committee shall be effective as of the date of the first meeting of the committee.~~

~~F. The chairperson of a standard advisory committee shall be appointed by the chairperson of the Commission.~~

~~G. A member of a standard advisory committee shall be subject to the provisions against conflicts of interest consistent with Article IX of these bylaws.~~

~~H. All meetings of standard advisory committees shall comply with the provisions of the Michigan Open Meeting Act, being Public Act 267 of 1976, as amended.~~

ARTICLE IV - MEMBERSHIP OF THE ~~CON~~ COMMISSION

A. Size and Composition

The ~~CON~~ Commission ~~shall~~ consists of 11 members ~~appointed by the Governor with the advice and consent of the Senate pursuant to~~as designated under Section 22211 of the Code.

~~1. Two individuals representing hospitals.~~

~~2. One individual representing physicians licensed under part 175 to engage in the practice of medicine.~~

~~3. One individual representing physicians licensed under part 175 to engage in the practice of osteopathic medicine and surgery.~~

~~4. One individual who is a physician licensed under part 170 or 175 representing a school of medicine or osteopathic medicine.~~

~~5. One individual representing nursing homes.~~

~~6. One individual representing nurses.~~

~~7. One individual representing a company that is self-insured for health coverage.~~

~~8. One individual representing a company that is not self-insured for health coverage.~~

~~9. One individual representing a nonprofit health care corporation operating pursuant to the nonprofit health care corporation reform act, 1980 PA 350, MCL 550.1101 to 550.1703.~~

~~10. One individual representing organized labor unions in this state.~~

B. Term of Office

Commission members will serve a term as set forth in Section 22211(3) of the Code.

~~1. Newly appointed Commissioners take office upon appointment of the Governor. Unless rejected by the Senate, Commissioners then serve until their term of office expires and their successor takes office or their resignation is accepted by the Governor.~~

~~2. The members of the CON Commission, with the exception of initial members, shall serve for a term of three years or until a successor is appointed.~~

~~C. Quorum, Voting Procedures, and Proxy Votes~~

~~1. A majority of the CON Commission members appointed and serving shall constitute a quorum. Final action by the CON Commission shall be only by affirmative vote of a majority of CON Commission members appointed and serving.~~

~~2. Actions not resulting in final action (including recommending action by the full commission or completing other planning tasks) may be made by a majority of those in attendance.~~

~~3. A CON Commission member shall not vote by proxy. A proxy of a CON Commission member shall not be seated, nor shall they vote, offer motions or second motions.~~

ARTICLE V~~I~~ - MEETINGS OF THE ~~CON~~ COMMISSION

A. Quorum, Voting Procedures, and Proxy Votes

1. Section 22213 of the Code defines a quorum for the Commission. With an 11 member Commission, a quorum is 6 of the 11 members appointed and serving.

2. Final action by the Commission shall be only by affirmative vote of a majority of the Commission members appointed and serving. Any action taken in the absence of a quorum is invalid. If the Commission properly notices a meeting under the Open Meetings Act, but lacks a quorum when it actually convenes, the Commission members in attendance may receive reports and comments from the public or from the Department, ask questions, and comment on matters of interest.

3. Commission members cannot assign a proxy.

B. Compliance ~~With~~with Open Meetings Act

The ~~CON~~ Commission ~~shall~~ must adhere to the provisions of the Michigan Open Meetings Act, ~~being Public Act 267 of~~ 1976 PA 267, as amended, MCL 15.261, et seg.

~~B~~C. Governance under Robert's Rules of Order Revised

The Commission's procedural activities ~~shall be~~are governed by Robert's Rules of Order Newly Revised ~~if, in so far as~~ they are consistent with state law and these ~~bylaws~~Bylaws.

~~C. Notice of Meetings~~

~~The Department shall make available the times and places of the meetings of the CON Commission. The Department shall also keep minutes of such meetings and a record of the actions of the CON Commission.~~

D. Regular and Special Meetings

1. In September, ~~The~~ the ~~CON~~ Commission ~~shall hold regular meetings quarterly at places and on dates fixed by the CON Commission~~must announce~~d in September, preceding each calendar year~~ the regular meeting dates for the following year. Special meetings may be called as provided for in Section 22213 of the Code.

2. ~~Special meetings may be called by the chairperson of the CON Commission, by not less than three CON Commission members, or by the Department.~~

3. A regular or special meeting of the ~~CON~~ Commission may be recessed and reconvened consistent with the provisions of the Michigan Open Meetings Act, ~~being Public Act 267 of~~ 1976 PA 267, as amended, MCL 15.261, et seg.

E. Meeting Attendance

1. ~~Members of the CON~~ Commission members are expected to attend all regular and special meetings except on those occasions where good cause exists.

2. When a Commission member ~~of the CON Commission is aware that he or she~~ will be unable to attend a regular or special meeting, every effort should be made to give advance notice to the Department, which ~~shall~~ must notify the Commission chairperson or vice-chairperson ~~of the CON Commission~~.

3. The Commission chairperson ~~of the CON Commission shall~~ determines whether ~~a~~ good cause exists for the absence of a member from a regular or special meeting of the ~~CON~~ Commission. When the attendance of the chairperson is under question, the responsibility for determining good cause falls to the Commission vice-chairperson ~~of the CON Commission~~.

4. Pursuant to the Code, ~~The~~ the Governor may remove a ~~CON~~ Commission member from office for failure to attend 3 consecutive meetings in a 1-year period. The Commission chairperson ~~or vice-chairperson of the CON Commission shall~~ must promptly inform the Governor's office (a) if a member fails to attend the statutory minimum number of consecutive meetings in a 1-year period, and (b) ~~of such situations, and shall~~ indicate ~~as to~~ whether good cause existed for such absences.

F. Teleconferencing

Commission members may participate in meetings by ~~Teleconferencing~~ teleconferencing ~~shall be allowed in accordance~~consistent with the Open Meetings Act (~~Public Act 267 of~~ 1976 PA 267, as amended, MCL 15.261. et seq). Upon approval of the Chairperson, ~~CON~~ Commission members may appear at a meeting via electronic device, including speaker phone or interactive television, provided that a quorum is present at the meeting site and all individuals attending the meeting can hear, and can be heard by, the Commissioner(s) attending via electronic device. Commission members participating in meetings by teleconference cannot use teleconferencing to vote but may speak on matters being considered.

G. Agenda and Background Materials

1. In consultation with the Department and other Commission members, the ~~Chairperson~~ chairperson ~~shall~~ must ~~determine~~ set a tentative agenda for each meeting.

2. No later than 7 days before each meeting, the Department must place the tentative agenda ~~shall be placed~~ on the appropriate section of the Department's Web site. ~~No later than 5 days prior to each meeting the text of any proposed or final actions and relevant background materials shall be delivered to each Commissioner (using overnight delivery or Email, as necessary) and shall be posted on the appropriate section of the Department's Web site.~~

3. No later than 5 days before each meeting, the Department must deliver the text for any CON review standards for proposed or final actions and relevant background to each Commissioner (using overnight delivery or Email, as necessary) and post it on the appropriate section of the Department's Web site. ~~Urgent~~ At the start of a meeting, the Commission, by unanimous approval, may add ~~action items~~CON review standards, that meet statutory requirements~~,~~ for proposed or final action, to the agenda~~, meeting the statutory requirements, may be added to the agenda, on the unanimous approval by the Commission at the start of a meeting~~.

ARTICLE VI~~I~~ - OFFICERS AND PROCEDURES FOR ELECTING OFFICERS

A. Election of Chairperson and Vice-Chairperson

~~At its first meeting and~~ On an annual~~ly~~ basis ~~thereafter~~, the ~~CON~~ Commission ~~shall~~ must elect a chairperson and vice-chairperson for a 1-year term not to exceed ~~three~~ 3 consecutive terms. The chairperson and vice-chairperson ~~shall~~ cannot be members of ~~separate~~ the same major political ~~parties~~party.

B. Procedures for Selecting Officers

1. ~~Nominations for officers may be made by a~~Any ~~CON~~ Commission member may nominate officers if the member is appointed and serving and ~~in attendance~~ attending ~~at~~ the meeting where the selection of officers is to occur.

2. ~~Election of o~~Officers ~~shall be determined by an affirmative vote of~~are elected by a majority vote by the ~~of CON~~ Commission members appointed and serving.

C. Responsibilities of Officers

1. The chairperson presides over Commission meetings. In ~~The~~ the chairperson's ~~or, in his or her~~ absence, the vice-chairperson ~~shall~~ presides over ~~the CON~~ Commission ~~at all its regular and special~~ meetings. ~~In the event that~~ If neither the chairperson nor vice-chairperson is able to preside

over any portion of a meeting ~~or a portion thereof~~, the remaining members of the ~~CON~~ Commission ~~shall~~ must select a temporary presiding officer.

2. In the chairperson's absence, the vice-chairperson or the temporary presiding officer will perform ~~The~~ the duties designated to the chairperson in the ~~Public Health~~ Code and these ~~bylaws~~Bylaws~~, in the absence of the chairperson shall be performed by the vice-chairperson or the temporary presiding officer~~.

D. Filling Vacancies in Officers

1. If the office of chairperson becomes vacant for any reason, the vice-chairperson ~~shall~~ must vacate the~~ir~~ vice-chairperson position and ~~become~~ serve as the chairperson ~~of the CON Commission, serving~~for the remaining months of the chairperson's ~~one~~1-year term.

2. If the office of vice-chairperson becomes vacant for any reason, the ~~CON~~ Commission ~~shall~~ must elect a new vice-chairperson by an affirmative vote of a majority of those members appointed and serving, and that person ~~shall~~ will serve the remaining months of the vice-chairperson's term.

3. If the offices of chairperson and vice- chairperson become vacant simultaneously, the ~~CON~~ Commission ~~shall~~ must conduct a special election to fill those positions. New officers ~~shall~~ must be elected by an affirmative vote of a majority of those members appointed and serving and they ~~shall~~ must serve the remaining months of the chairperson's and vice-chairperson's term.

ARTICLE VII – COMMITTEES

A. Standing New Medical Technology Advisory Committee (NEWTAC)

Composition and duties of the NEWTAC are set forth in Section 22241 of the Code.

B. Standard Advisory Committee (SAC)

If the Commission determines it necessary, it may appoint a SAC to assist in the development of proposed CON review standards in accordance with Section 333.22215(1)(I).

1. The Commission must adopt the duties for a SAC. The duties of the SAC must be defined in a written charge. The written charge to the SAC may be adopted by vote of the Commission, or the Commission may instruct the

chairperson to write the charge, consistent with the language adopted by the Commission.

2. The term of any SAC expires 6 months from the first meeting of the SAC or at an earlier date as specified by the Commission.

3. The chairperson appoints the members of a SAC consistent with statutory requirements and the criteria outlined in this subpart.

a. The Department determines whether a candidate for a SAC meets the following criteria:

i. The candidate has not served on more than 2 SACs within any 2-year period.

ii. The candidate is not a lobbyist registered under 1978 PA 472, MCL 4.411 TO 4.431.

iii. The candidate is not affiliated with a program with a Letter of Intent (LOI) or a pending application in the CON process related to the standard(s) being reviewed.

b. A SAC consists of a 2/3 majority of experts with professional competence in the subject matter of the proposed standard. The Department determines whether a candidate seeking to be appointed as an expert to a SAC meets the following criteria:

i. The candidate is a clinician, e.g., doctor, nurse, or other health care professional, who has specific education, training, and experience in the service being considered; or the candidate is a representative of an organization concerned with licensed health facilities, e.g., administrator or a specialist in the subject matter of the standard being reviewed, who have specific education, training, and experience in the service being considered.

ii. Professional competence demonstrated by relevant professional activity over a majority of the last five years.

c. A SAC includes representatives of health care provider organizations concerned with licensed health facilities or licensed health professions, as well as representatives of organizations concerned with health care consumers, and the purchasers and payers of health care services.

d. Only one employee, director, or officer of any one health system, either directly or through the subsidiaries of a system can be appointed as a

member of the same SAC. For purposes of these Bylaws, "health system" means facilities where health care is provided and includes without limitation hospitals, nursing homes, county medical care facilities, home health agencies, hospices, out-patient surgical facilities, laboratories, rural health clinics, freestanding surgical units, ambulatory surgical units, and end stage renal disease and dialysis facilities.

4. The Commission chairperson appoints the chairperson of a SAC.

C. Members of the NEWTAC and a SAC are subject to the following provisions:

1. Conflicts of interest consistent with Article IX of these Bylaws.

2. Teleconferencing consistent with Article V(F) of these Bylaws.

3. Michigan Open Meetings Act, 1976 PA 267, as amended, MCL 15.261, et seq.

ARTICLE VIII - ~~PARLIAMENTARY~~ PROCEDURE AND LEGAL COUNSEL

A. ~~The Attorney General of the State of Michigan, or his or her duly designated Assistant Attorney General, shall serve as parliamentarian for the CON Commission. The duties of the parliamentarian shall be to advise the presiding officer with respect to any matters pertaining to parliamentary procedure.~~

B. ~~Any~~The presiding officer will use the laws of the State, these Bylaws, and Robert's Rules of Order Newly Revised to resolve any question arising concerning procedure at a meeting of the ~~CON~~ Commission ~~shall be resolved by the presiding officer in accordance with the laws of the State, these bylaws, and Robert's Rules of Order Revised~~.

~~C~~B. The Attorney General of the State of Michigan, or ~~his or her~~the duly designated Assistant Attorney General, ~~shall~~ serve~~s~~ as legal counsel to the ~~CON~~ Commission.

ARTICLE IX - STANDARDS OF CONDUCT BY ~~CON~~ COMMISSION MEMBERS AND CONFLICT OF INTEREST PROVISIONS

A. ~~CON~~ Commission members are subject to the provisions of:

1. 1968 PA 317, MCL 15.321 to 15.330 (contracts of public servants with public entities);

2. 1973 PA 196, MCL 15.341 to 15.348 (code of ethics for public officers and employees); and

3. 1978 PA 472, MCL 4.411 to 4.431, (lobbyists and lobbying regulation~~);~~).

B. Definition - Conflict of Interest

1. Under the State Ethics Act, 1973 PA 196, MCL 15.341, et seq, and in accordance with the Advisory Opinion of the State Board of Ethics of November 5, 2004, a conflict of interest for ~~CON~~ Commission members ~~shall~~ exists when the individual member has a financial or personal interest in a matter under consideration by the ~~CON~~ Commission. The personal interest of a ~~CON~~ Commission member includes the interest of the member's employer, even though the member may not receive monetary or pecuniary remuneration as a result of an adopted CON review standard.

2. ~~CON~~ A Commission member~~s shall~~ does not ~~be in violation~~ violate ~~of~~ the State Ethics Act~~, supra,~~ if the member abstains from deliberating and voting upon ~~review standards~~the matter in which the member's personal interest is involved.

3. ~~CON~~ A Commission member~~s~~ may deliberate and vote on ~~standards~~ matters of general applicability~~; that is, those standards~~ that do not exclusively benefit certain health care facilities or providers who employ the ~~CON~~ Commission member, even if the ~~standard of general applicability would benefit~~matter involves the member's employer or those for whom the member's employer does work.

4. Deliberating includes all discussions of the pertinent subject matter, even before a motion being made.

C. Procedures - Conflict of Interest

1. A ~~CON~~ Commission member ~~shall~~ must disclose ~~that he or she~~any ~~has a~~ potential conflict of interest~~,~~ after the start of a meeting, ~~at the commencement of~~ when the Commission begins to consider~~ation of~~ a substantive matter ~~before the CON Commission~~, or, where consideration has already commenced, when~~, at the point where~~ a conflict or potential conflict of interest becomes apparent to the member.

2. After a meeting is called to order and the agenda reviewed, the chairperson ~~shall~~ must inquire whether any Commission member has a conflict or potential conflict of interest with regard to any matters on the agenda.

3. ~~Prior to a vote on a substantive matter before the CON Commission, the presiding officer shall inquire of the membership as to the existence of a conflict of interest.~~

~~4. A conflict of interest shall not affect the existence of a quorum for purposes of a vote~~ A Commission member who is disqualified from deliberating and voting on a matter under consideration due to a conflict of interest may not be counted to establish a quorum regarding that particular matter.

~~5~~4. Where a Commission member has not discerned ~~that she/he may have~~ any conflict of interest ~~and must voluntarily abstain from discussion and vote~~, any other Commission member may raise a concern ~~as to~~ whether another member has a conflict of interest on a ~~substantive~~ matter. If a second member joins in the concern, ~~there shall be~~the Commission must discuss~~ion~~ and ~~a~~ vote on whether the member has a conflict of interest ~~prior to~~before continuing discussion or taking any action on the ~~substantive~~ matter under consideration. The question of conflict of interest ~~shall be~~is settled by an affirmative vote of a majority of those ~~CON~~ Commission members appointed and serving, excluding the member or members in question.

~~6~~5. The minutes of the meeting ~~shall~~ must reflect when a conflict of interest had been determined and that an abstention from deliberation and voting had occurred.

ARTICLE X - AMENDMENTS OF BYLAWS

A. Any amendments to these ~~bylaws~~Bylaws ~~shall~~ must be proposed by the ~~CON~~ Commission or presented in writing to the ~~CON~~ Commission by the Department at least 30 days in advance of the meeting where final action is scheduled to be taken.

B. ~~Any amendments to these bylaws shall be deemed to be approved upon an affirmative vote of a majority of the CON Commission members appointed and serving.~~ Amendments to the ~~bylaws~~Bylaws ~~shall~~ become effective upon approval or on ~~such~~ a later date ~~as is~~if specified within the amendments.

SUMMARY OF PROPOSED REVISIONS TO THE CERTIFICATE OF NEED (CON) COMMISSION BYLAWS

1. Re-organized, clarified, and streamlined Articles by removing those requirements that are already in statute.

2. Under Teleconferencing, added "Commission members participating in meetings by teleconference cannot use teleconferencing to vote but may speak on matters being considered." The Commission's current governing statute does not expressly authorize the use of electronic communication devices for participating in Commission meetings. Express statutory authorization is needed before members can use teleconferencing to vote at meetings.

3. Added language referencing the Standing New Medical Technology Advisory Committee (NEWTAC) and its composition and duties.

4. Added language referencing a Standard Advisory Committee (SAC) and its composition and duties.

5. Modified the language so that the Chairperson serves as parliamentarian, not the Attorney General of the State of Michigan, or his or her duly designated Assistant Attorney General.

Note: New or revised standards may include the provision that make the standard applicable, as of its effective date, to all CON applications for which a final decision has not been issued.

Attachment N

CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2009												2010											
	J*	F	M*	A	M	J*	J	A	S*	O	N	D*	J*	F	M*	A	M	J*	J	A	S*	O	N	D*
Air Ambulance Services										PH	•	•	• R F											
Bone Marrow Transplantation (BMT) Services**	• R	•	• R	•	•	▮	▮	▮	▮	▮	▮	• —	•	P •	• ▲ F									
Computed Tomography (CT) Scanner Services										PH •	•	•	• R											
Heart/Lung and Liver Transplantation Services**	• R	•	•	▮	▮	▮	▮	▮	▮	▮	•	• —	•	P •	• ▲ F									
Magnetic Resonance Imaging (MRI) Services	• R	•	•	•	•	• —	• P	•	• ▲ F R	•	•	• —	•	P •	• ▲ F									
Neonatal Intensive Care Services/Beds (NICU)										PH •	•	•	• R											
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups										PH •	•	•	• R											
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units										PH •	•	•	• R											
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 R
FY2009 CON Annual Activity Report										•	•	• R												
Administrative Rules	•	•	• R	•	•	• R	•	•	• R	•	•	• R	•	•	• R D									

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 9, 2009

Updated December 14, 2009

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 & Professions Administration, CON Policy Section, 7th Floor Capitol View Bldg., 201 Townsend St., Lansing, MI 48913, 517-335-6708, www.michigan.gov/con.

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

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	June 4, 2004	2010
Bone Marrow Transplantation Services	November 13, 2008	2012
Cardiac Catheterization Services	February 25, 2008	2011
Computed Tomography (CT) Scanner Services	June 20, 2008	2010
Heart/Lung and Liver Transplantation Services	June 4, 2004	2012
Hospital Beds and Addendum for HIV Infected Individuals	March 8, 2007	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)	November 13, 2007	2010
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	June 20, 2008	2010
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	2010

*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.