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

Tuesday January 29, 2013

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

APPROVED MINUTES

I. Call to Order & Introductions

Chairperson Falahee called the meeting to order @ 9:39 a.m.

A. Members Present:

Gail J. Clarkson RN
James B. Falahee, Jr., JD, Chairperson
Charles Gayney
Edward B. Goldman
Robert Hughes
Marc Keshishian, MD, Vice-Chairperson
Brian Klott
Gay L. Landstrom, RN
Suresh Mukherji, MD

B. Members Absent

Kathleen Cowling, DO
Luis Tomatis, MD

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Community Health Staff Present:

Tulika Bhattacharya
Natalie Kellogg
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Goldman, seconded by Commissioner Gayney, to approve the modified agenda (with the removal of Heart/Lung and Liver Transplantation Services) as presented. Motion Carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of December 13, 2012

Motion by Commissioner Clarkson, seconded by Commissioner Mukherji, to approve the minutes of December 13, 2012 as presented. Motion Carried (see Attachment A).

V. Air Ambulance (AA) Services – October 10, 2012 Public Comment Period Summary and Report

Ms. Rogers gave a brief overview of the Department's recommendations regarding AA Services (see Attachment B).

A. Public Comment:

None.

B. Commission Discussion

Discussion followed.

C. Commission Action

The Commission asked the Department to gather additional information regarding the following questions to bring back to a future meeting:

1. What can the State regulate outside the federal USDOT oversight (General Counsel Memo dated March 9, 2012)?
2. How many states regulate AA Services through EMS provider licensure?
3. What other government bodies provide oversight?

VI. Computed Tomography (CT) Scanner Services – October 10, 2012 Public Comment Period Summary & Report

Ms. Rogers gave a brief overview of the Department's recommendations regarding CT Scanner Services (see Attachment C).

A. Public Comment:

Karen Kippen, Henry Ford Health Systems
Robert Meeker, Spectrum Health

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Goldman, seconded by Commissioner Landstrom, to form a workgroup to look at CT scanner issues and delegate to the Chair and Vice-Chair to draft the charge. Commissioner Mukherji will chair the workgroup. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstained.

VII. Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services\ Units- October 10, 2012 Public Comment Period Summary and Report

Ms. Rogers gave a brief overview of the Department's recommendations regarding UESWL Services/Units Standards (see Attachment D).

A. Public Comment

Jorgen Madsen, Great Lakes Lithotripsy
James Bour, Greater Michigan Lithotripsy
Ted Amland, AKSM/Greater MI Lithotripsy (see Attachment E)
Michael Sandler, MD, Henry Ford Health Systems

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Goldman, seconded by Commissioner Clarkson, for the creation of a workgroup to determine if the service should be de-regulated, or if continuing to regulate, review the volume criteria for expansion. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstained.

Chairperson Falahee will name a chair for the workgroup.

Break @ 11:11 a.m. – 11:29 a.m.

VIII. Neonatal Intensive Care Services & Beds (NICU) – October 10, 2012 Public Comment Period Summary & Report

Ms. Rogers gave a brief overview of the Department's recommendations regarding NICU Services & Beds Standards (see attachment F).

A. Public Comment

Trudy Esch, MDCH (see Attachment G)

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Vice-Chairperson Keshishian, seconded, by Commissioner Landstrom, creation of a workgroup to review and recommend if Level II NICU designations should be included under CON and the requirements that would need to be added to the standards. Commissioner Landstrom will chair this workgroup. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstained.

IX. Nursing Home and Hospital Long-Term Care Unit (NHLTCU) Beds and Addendum for Special Population Groups – October 10, 2012 Public Comment Period Summary & Report

Ms. Rogers gave a brief overview of the Department's recommendations regarding NHLTCU Services & Beds Standards (see attachment H).

A. Public Comment:

Lisa Ashley, Hospice & Palliative Care Assoc. of MI
Lody Zwarensteyn, Alliance for Health
Pat Anderson, Health Care Assoc. of Michigan (see Attachment I)
Robert Meeker, Spectrum Health

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Gayney, seconded by Commissioner Klott, to establish a Standard Advisory Committee (SAC) and delegate the drafting and approval of the charge and the seating of the SAC to the Chair and Vice-Chair with the assistance of the Department. Motion carried in a vote of 9- Yes, 0-No, and 0- Abstained.

X. MDCH Recommendations for Deregulation of CON Covered Services

A. Bone Marrow Transplantation (BMT) Services

Public Comment:

Gregory Yanik, MD, University of Michigan (see Attachment J)
Joe Uberti, MD, Karmanos Cancer Center
Karen Kippen, HFHS
Sean Gehle, Ascension Health
John Magenau, U of M Health Systems
Richard Fennell, Spectrum Health
Robert Meeker, Spectrum Health
Dennis McCafferty, Economic Alliance for Michigan (EAM)

Discussion followed, and the below items were raised:

1. Compare BMT services per 1 million population in CON vs. Non-CON states.
2. Compare drive time from cities with 100,000 population for BMT Services in CON vs. Non-CON states.
3. Average volume of BMT procedures nationally in CON vs. Non-CON states?
4. Clarification on costs of BMT services.

Chairperson Falahee asked the Commissioners to come back in March with any additional questions and information.

XI. Commission Communication

Chairperson Falahee gave a brief overview and update on a proposed Legislative Day.

XII. Review of Commission Work Plan

A. Commission Discussion

Ms. Rogers provided an overview.

After discussion, Vice-Chairperson Keshishian recommended implementing the review of Standards in the following order: NICU workgroup, CT scanner services workgroup, NHLTCU SAC, and UESWL workgroup.

For the upcoming March meeting, Open Heart Surgery (OHS) and Magnetic Resonance Imaging (MRI) Standards will be reviewed for proposed action, and MRT will be reviewed for final action.

B. Commission Action

Motion by Commissioner Goldman, seconded by Commissioner Klott to approve the Work Plan as discussed. Motion carried in a vote of 9- Yes, 0- No, and 0- Abstained.

XIII. Future Meeting Dates – March 28, 2013, June 13, 2013, September 26, 2013, & December 12, 2013

XIV. Adjournment

Motion by Commissioner Gayney, seconded by Commissioner Goldman, to adjourn the meeting at 1:15 p.m. Motion Carried in a vote of 9-Yes, 0-No, and 0- Abstain.

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

Thursday December 13, 2012

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

DRAFT MINUTES

I. Call to Order & Introductions

Chairperson Falahee called the meeting to order @ 9:32 a.m.

A. Members Present:

Gail J. Clarkson RN, Medilodge
James B. Falahee, Jr., JD, Chairperson
Charles Gayney
Edward B. Goldman
Robert Hughes
Marc Keshishian, MD, Vice-Chairperson
Brian Klott
Suresh Mukherji, MD
Kathleen Cowling, DO

B. Members Absent

Gay L. Landstrom, RN
Suresh Mukherji, MD
Luis Tomatis, MD

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Community Health Staff Present:

Tulika Bhattacharya
Scott Blakeney
Natalie Kellogg
Abigail Mitchell
Beth Nagel
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Goldman, seconded by Commissioner Hughes, to approve the agenda as presented. Motion Carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of September 27, 2012

Motion by Commissioner Clarkson, seconded by Commissioner Gayney, to approve the minutes of September 27, 2012 as presented. Motion Carried (see Attachment A).

V. Introduction of James Haveman, Director, Michigan Department of Community Health (MDCH)

Director Haveman introduced himself to the CON Commission and gave a brief introductory statement.

VI. Bone Marrow Transplantation (BMT) Services - Technical Edits

Ms. Rogers gave a brief overview of the public hearing testimony on the proposed changes to BMT Services Standards (see Attachment B).

A. Public Comment:

None.

B. Commission Discussion

None.

C. Commission Final Action:

Motion by Commissioner Goldman, seconded by Commissioner Cowling, to approve the proposed language and move it forward to the Joint Legislative Committee (JLC) and Governor for the 45-day review period. Motion Carried in a vote of 8- Yes, 0- No, and 0- Abstained.

VII. Psychiatric Beds & Services Workgroup Report

Ms. Rogers gave a brief overview of the public hearing testimony on the proposed changes to Psychiatric Beds and Services Standards (see Attachment C).

A. Public Comment

None.

B. Commission Discussion

Discussion followed.

C. Commission Final Action

Motion by Commissioner Cowling, seconded by Commissioner Clarkson, to approve the proposed language and move it forward to the JLC and Governor for the 45-day review period. Motion Carried in a vote of 8- Yes, 0- No, and 0- Abstained.

Motion by Commissioner Cowling, seconded by Vice-Chairperson Keshishian, to make the Psychiatric Bed Need numbers effective immediately. Motion Carried in a vote of 8- Yes, 0- No, and 0- Abstained.

VIII. Open Heart Surgery (OHS) Standard Advisory Committee (SAC) Final Report and Draft Language

Dr. Sell presentated the OHSSAC's final report and recommendations (see Attachment D).

Ms. Rogers gave a brief overview of the draft language and the process.

A. Public Comment:

Melissa Cupp, Wiener Assoc.
Dennis McCafferty, Economic Alliance for Michigan (EAM)
Dr. Richard Prager, University of Michigan (U of M)

B. Commission Discussion

Discussion followed.

C. Commission Proposed Action

Motion by Commissioner Goldman, seconded, by Commissioner Hughes, to not take proposed action nor send the standards for public hearing, but to have the Department review Section 7 for clarity and propose a recommendation for the maintenance volume. Motion Carried in a vote of 8- Yes, 0- No, and 0- Abstained.

Motion by Vice-Chairperson Keshishian, seconded by Commissioner Klott, to amend the OHS Standards proposed language with the addition of CMS regulation language for Transcatheter Aortic Valve Implantation

(TAVI) procedures. Motion failed in a vote of 4- Yes, 4- No, and 0- Abstained.

Public Comment:
Melissa Cupp, Wiener Assoc.
Dr. Gaetano Paone, Henry Ford Health Systems (HFHS)

Break @ 12:00 p.m. - 12:23 p.m.

IX. Megavoltage Radiation Therapy (MRT) Workgroup Report and Draft Language

Commissioner Cowling declared a conflict of interest.

Vice-Chairperson Keshishian presented the results and conclusions of the MRT workgroup (see Attachment E).

A. Public Comment:

Nancy List, Covenant Health
Greg Dobis, McLaren Health

B. Commission Discussion

Ms. Rogers gave a brief overview of the draft language and changes to the standards (see Attachment F).

C. Commission Proposed Action

Motion by Commissioner Goldman, seconded by Commissioner Gayney, to approve the proposed MRT language and move it forward for public hearing and the JLC. Motion carried in a vote of 7- Yes, 0-No, and 1- Abstained.

X. Standing New Medical Technology Advisory Committee (NEWTAC)

Vice-Chairperson Keshishian stated no new updates.

XI. Legislative Report

Mr. Blakeney gave a brief update.

XII. Administrative Update

A. Planning & Access to Care Section Update

Ms. Nagel stated there were no updates.

B. CON Evaluation Section Update

Ms. Bhattacharya gave a brief overview on the FY2012 CON Annual Activity Report (see Attachment G). Mr. Blakeney gave comment on increasing the CON fees.

Ms. Bhattacharya gave an update on both compliance and quarterly performance activity (see Attachments H & I).

XIII. 2-Year Report to the Joint Legislature Committee (JLC)

A. Commission Discussion

Chairperson Falahee provided an overview and discussion followed (see Attachment J).

B. Commission Action

Motion by Commissioner Goldman, and seconded by Commissioner Cowling, to approve the JLC report with amendments and authorize the Department to use electronic signatures. Chairperson Falahee and Vice-Chairperson Keshishian will give final approval. Motion carried in a vote of 8- Yes, 0-No, and 0- Abstained.

XIV. Legal Activity Report

Mr. Potchen gave a brief status update on the legal activities (see Attachment K).

XV. Future Meeting Dates

A. January 29, 2013 (Special CON Commission Meeting), March 28, 2013, June 13, 2013, September 26, 2013, & December 12, 2013

XVI. Public Comment

Dr. Michael Sandler, HFHS

XVII. Review of Commission Work Plan

Ms. Rogers gave a brief overview of the Work Plan (see Attachment L).

A. Commission Discussion

None.

B. Commission Action

Motion by Commissioner Gayney, seconded by Commissioner Cowling, to approve the work plan as presented. Motion Carried in a vote of 8- Yes, 0- No, and 0- Abstain.

XVIII. Adjournment

Motion by Commissioner Goldman, seconded by Commissioner Klott, to adjourn the meeting @ 1:02 p.m. Motion Carried in a vote of 8- Yes, 0- No, and 0- Abstain.

MDCH Recommendations for CON Standards Scheduled for 2013 Review

Air Ambulance Services			
Should the covered service continue to be regulated?	No.		
Identified Issues	**Does this issue require further review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Air Ambulance Standards are preempted by the Federal Aviation Administration (FAA).	Yes	Proposed Action at the March CON Commission meeting to de-regulate this service.	The Commission should consider de-regulation of this service as it is already federally regulated. Currently, the Department is applying the existing Standards and is applying the federal Declaratory Ruling, which doesn't allow states to regulate need.

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 2013.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 10 - 24, 2012. Testimony was received from three (3) organizations and is summarized as follows:

Sean Gehle, Ascension Health

- Continues to support regulation of these services and does not recommend any changes to the current standards.

Robert Meeker, Spectrum Health

- Continues to support regulation of these services and does not recommend any changes to the current standards.

History 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. However, at this time, the Commission approved a motion to table the discussion of AA Services until January 28, 2010 when the AA Services Standards were up for review again. The consensus was based on federal actions, need requirements cannot be enforced. On June 10, 2010, the Commission took final action on previously proposed changes. If the federal status regarding need would change in the future, then Michigan's CON review standards would already contain need requirements. The Department has continued to apply the Declaratory Ruling as appropriate.

Summary of FAA Exemption:

The US Department of Transportation (US DOT), in attempting to clarify the limits of federal regulation, has indicated that the while the FAA regulates air safety, states are free to regulate medical safety.

The areas where federal preemption has been asserted are as follows: requirement for 24/7 service, requirement for a CON, regulation of rates, response times, bases of operation, bonding requirements, and accounting and reporting systems, matters concerning aviation safety including equipment, operation, and pilot qualifications, requirements for certain avionics/navigation equipment, requirements for general liability coverage, and safety aspects of medical equipment installation, storage on aircraft and safety training of medical personnel. Court decisions have found in favor of the Helicopter Emergency Medical Service (HEMS) programs when states have required a CON.

Further, the Federal district court in Med-Trans found a State Certificate of Need program requiring an air ambulance provider to obtain a "valid EMS Provider License" and have an "EMS Peer Review Committee" in place to operate as a Specialty Care Transport Program preempted under Federal law. 581 F.Supp.2d at 737. Under the facts of that case, the court found that the challenged regulations could be used to affect entry into the air ambulance market for reasons other than medical ones.

The court stated: The collective effect of the challenged regulations is to provide local government officials a mechanism whereby they may prevent an air carrier from operating at all within the state.... The court therefore finds that the [regulations] are preempted to the extent that they require approval of county government officials which, if denied, would preclude plaintiff from operating within the state. 583 F.Supp.2dat738.[1]

2011 AA Service Data

AA Services are regulated by 7 of the 37 CON States. There have been 9 applications since 2009 to change or provide AA service. The Department collected AA data via the web-based annual survey in 2011. There were nine (9) providers with a total of 11 primary air ambulances. The 2011 data by facility is as follows:

[1] http://proteus.howdyhost.net/pipermail/board_lists.acctforpatients.org/attachments/20120315/536a33ea/attachment-0001.pdf

2011 AA Service Data

Facility Number	Facility Name	Number of Helicopters			Number of Patient Transports			
		Type	Primary	Back-up	Pre-Hospital	Inter-Facility	Advance Life	Total
19.C004	LIFENET OF MICHIGAN	M	1	0	26	174	0	200
28.C001	NORTH FLIGHT, INC	M	1	0	60	101	7	168
39.1013	WEST MICHIGAN AIR CARE	M	1	1	99	427	0	526
41.0040	SPECTRUM HEALTH BUTTERWORTH	H	2	0	112	486	7	605
50.C688	SUPERIOR AIR GROUND	M	1	0	0	201	0	201
73.8653	ST. MARY'S OF MICHIGAN – FLIGHTCARE	M	1	1	34	295	1	330
73.C005	LIFENET	M	1	0	333	46	0	379
81.0060	UNIVERSITY OF MICHIGAN HOSPITALS	H	2	1	73	745	2	820
81.1007	MIDWEST MEDFLIGHT	M	1	1	14	208	0	222
99.0002	PROMEDICA TRANSPORTATION NETWORK	M	1	3	10	197	0	207
99.1006	ST. VINCENT MEDICAL CTR/LIFE FLIGHT	M	2	0	55	28	0	83
STATE TOTAL		**11 Facilities**	**14**	**7**	**816**	**2,908**	**17**	**3,741**

MDCH Staff Recommendations

The Department recommends de-regulation of Air Ambulance Service.

Aviation safety decisions are separate from medical decisions. The decision to conduct a flight with a patient on board does not mean that flight safety will be compromised in any way. Need determination requirements are preempted by FAA regulations. Therefore safety, equipment, and staffing requirements are the only aspects to be regulated by CON within the State of Michigan.

Deregulating this covered clinical service would reduce duplicating AA regulations within State and Federal governments.

MDCH Recommendations for CON Standards Scheduled for 2013 Review

Computed Tomography (CT) Standards			
Should CT services continue to be regulated under CON?	Yes.		
Identified Issues	**Issue Recommended for Review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Allowance of Mobile dental CT scanners	Yes	Formation of a workgroup	A concern raised is the potential for escalation of the utilization/proliferation of units.
Review the weights to balance CMS bundling issues	Yes	Formation of a workgroup	The Department modified the Standards in 2011 to accommodate the bundling issue, but agreed to review this further.
Develop language to allow exemptions for dedicated research CT scanners	Yes	Formation of a workgroup	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.
Develop language to allow exemptions for CT-Angiography	No	None	Hybrid modality can be a billable procedure, and therefore, should continue to be included within annual maintenance volume requirements.
Make technical changes and updates that provide uniformity in all CON standards	Yes	MDCH to offer recommendations	
Add language similar to that of MRI and PET to allow existing host sites to be added to different existing networks within the initiation section	Yes	MDCH to offer recommendations	

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 2013.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 10 - 24, 2012. Testimony was received from seven (7) organizations and is summarized as follows:

1. *Steven Szelag, University of Michigan Health System (UMHS):*
    - Supports overall regulations for CT services.
    - The current definition does not exempt CT scanners used in conjunction with Angiography or Interventional Radiology equipment. UMHS encourages volume exemptions when CT scanners are used in a subsidiary capacity with any therapeutic and/or diagnostic modality.
    - To be consistent with other CON Standards such as MRI or PET; regulations should be developed to allow providers the opportunity to acquire a research CT scanner. This would significantly increase one's ability to evaluate new treatment methods, including drugs, by increasing the speed and reducing the cost for such clinical trials.

2. *Robert Meeker, Spectrum Health :*
    - Proposes that the definition of a CT procedure be addressed.
    - The current definition for a "Billable Procedure" was proposed as a temporary 'fix' to address a change in CMS billing definitions.
    - Recommends defining a CT procedure independently, following the manner in which other CON standards define the counting of procedures and allow for the actual portrayal of CT equivalents (and therefore volumes) for each CT scanner with an organization.

3. *Anny Arana, Allegiance Health:*
    - Recommends that the CT volume requirements and conversion factors be reviewed for updates, for example average scan times 10 years ago have decreased from 1 hour to an average of 15-20 minutes, increasing the scans per CT machine.
    - Recommends adding language to the "special needs patient" definition to include trauma patients.

4. *Sean Gehle, St. John Providence Health System*
    - Supports continued regulation of CT services.
    - Recommends increasing volume requirements to initiate a CT service.

- Recommends revising language in section 13 to include hospital-based portable CT scanners as a permanent part of initiation, expansion, replacement, and acquisition.

5. *Monica Harrison, Oakwood Healthcare, Inc.*
    - Recommends the formation of a workgroup to further define "CT procedure" outside of billing parameters.

6. *Karen Kippen, Henry Ford health System (HFHS)*
    - Recommends that the Commission convene a workgroup to look at alternative methods of measuring usage for CT scanners.
    - Resolutions that are created may be applicable for other covered services, as bundled payments may impact MRI or PET billing.

7. *Patrick O' Donovan, Beaumont Health System*
    - Supports continued regulation of CT services.
    - Recommends no specific changes to these standards at this time.

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 2011

Currently, based on the 2011 Annual Survey data, there are 379 fixed CT units in the State of Michigan. Additionally, there are seven (7) mobile CT units in the State as well.

In 2011, there were 2,244,953 scans provided by hospitals, freestanding facilities, and host sites. Additionally in 2010, there were 7,613 scans provided by mobile providers.

MDCH Staff Recommendations

MDCH recommends that the Commission consider continued regulation and the necessity of addressing the identified issues. Further, MDCH recommends that the issues to be addressed through the formation of a workgroup.

MDCH Recommendations for CON Standards Scheduled for 2010 Review

Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Standards			
Should there be continued regulation of UESWL under CON?	No. MDCH recommends that the Commission consider deregulating UESWL services.		
Identified Issues	**Issue Recommended for Review?**	**Recommended Course of Action to Review Issues:**	**Other/Comments:**
Decrease the volume requirement for expansion of a mobile lithotripsy service.	No	None	There is no evidence of statewide implications or impact of the change on a statewide basis.

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 2013.

Public Comment Period Testimony
The Department held a Public Comment Period to receive testimony regarding the Standards on October 10 - 24, 2012. Testimony was received from six (6) organizations and is summarized as follows:

1. *Patrick O' Donovan, Beaumont Health System:*
    - Supports the continued regulation of this lithotripsy services.
    - Recommends decreasing the volume requirement for expansion of a mobile lithotripsy route.
    - Additionally, they believe that without adequate lithotripsy access, patients with kidney stones may have to undergo invasive ureteroscopy procedures.

2. *Jorgen Madesen, United Medical Systems/Great Lakes Lithotripsy:*
    - Strongly believes that there should be continued regulation of the UESWL services, because lithotripsy is an outpatient service with a high potential for abuse. Unlike many other health services, lithotripsy is not considered a "designated health service" under Stark and physician self-referral is not restricted under those regulations.
    - CON has lowered costs to providers within Michigan: Nationally, the charge by a mobile lithotripsy provider to the facility receiving

service is between $2,200 and $2,400 per procedure. However, in Michigan the rate charged is between $1,400 and $1,500 per procedure.
- Further, CON in Michigan acts as a deterrent for physicians who may otherwise have been lured into less than ideal schemes to bring in revenues.

3. *Sean Gehle, Ascension Health*
    - Supports the continued regulation of lithotripsy services and does not recommend any changes to the current standards.

4. *Karen Kippen, Henry Ford Health System*
    - Continues to support regulation of lithotripsy services because the current standards encourage and allows many facilities to share equipment.
    - By sharing equipment, and the technologist that operates the equipment, also helps to ensure high quality service by maintaining consistent and relatively high volumes performed by the same technologists.
    - Because lithotripsy is not covered by Stark regulations, the CON regulations help to reduce physician self-referral and keep the service in the most appropriate setting.

5. *Robert Meeker, Spectrum Health*
    - Continues to support regulation of lithotripsy services.
    - Strongly urges the Commission consider reducing the volume requirement for expanding the number of lithotripsy machines on a given mobile route.
    - The current level of 1800 procedures per machine per year is unrealistically high and inhibits the ability of mobile lithotripsy providers to adequately serve the needs of patients.

6. *Ted Amland, Greater Michigan Lithotripsy*
    - Supports continued regulation of lithotripsy services.
    - Recommends reducing the volume requirement to 1,200 to expand a mobile route, which is more consistent with national experiences.
    - Proposes a rural adjustment factor of two (2) be applied to rural host sites, both those currently providing and those applying to initiate lithotripsy services.
    - Proposes allowance for using a temporary lithotripsy unit during downtimes for repairs, without having to apply for an emergency CON. This could potentially be addressed by allowing existing units to cross HSA boundaries.

Summary of Public Input:

Five (5) organizations 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, and UESWL and other outpatient procedures are typically areas where abuse of this nature can occur. Proponents of continued regulation stated that a proliferation of equipment would occur if deregulation took place, and that CON provides an oversight role in UESWL treatments.

Regulation of Covered Service

Out of 36 states with CON programs, Michigan is one of 15 states which regulate Lithotripsy Services within CON.

UESWL Survey Data for 2011:

Facility No.	Type	Facility Name:	# Units	# Procedures
33M147	M	Great Lakes Lithotripsy	1	1,521
33M023	M	Great Lakes Lithotripsy, LLC	2	2,545
33M074	M	Great Lakes Lithotripsy, LLC	1	2,438
33.M103	M	Michigan CON, LLC	2	2,186
99.M167	M	Greater Michigan Lithotripsy	1	1,141
41M165	M	Spectrum Health – Butterworth	1	1,108
63M164	M	William Beaumont Hospital	1	1,067
		TOTAL	**9**	**12,006**

Volume Requirement for Expansion

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 unit during the most recent 12-month period for which the Department has verifiable data.

In looking at the 2011 survey data, one of the nine (9) Central Service Coordinators (CSCs) would meet the current volume requirement for expansion.

For the most part, all are averaging a minimum of 1,334 procedures a year per unit.

MDCH Staff Recommendations

MDCH recommends de-regulation of UESWL services. MDCH has recommended deregulation of UESWL three times; 2005, 2007 and 2010. The MDCH recommendations are based on the fact that UESWL is well-established, it is a low-cost service, and current data suggests there is adequate access throughout the state.

Reimbursement rates for Lithotripsy have decreased: Most states do not regulate the purchase of lithotripters (or other urologic technologies) with CON.[1] Thus, if the treatment of genitourinary stones were supply sensitive then, we would have expected to see national capacity exceed the amount required by population health needs. Current data shows that reimbursement rates for lithotripsy have decreased, which suggests that abuse has not occurred nationally in unregulated areas. It has been noted to the Commission by public input that the cost of UESWL is lower in Michigan than in other states. MDCH, however, found that Michigan's costs are very near the national average.

Reimbursement policies limit physician office use: The Center for Medicare and Medicaid services (CMS) current reimbursement methodology effectively forces lithotripsy services provided to Medicare beneficiaries to be furnished "under arrangements with a hospital outpatient department. The Medicare reimbursement system (as well as certain technological considerations) strongly discourages the provision of lithotripsy services in a physician office setting." [2]

Further, the CMS methodology was developed because the established global rate for lithotripsy under Medicare's physician fee schedule does not currently incorporate a physician's overhead cost of the lithotripsy equipment.[3] According to the 2012 Medicare Physician Fee Schedule Payment Rate for Lithotripsy, extracorporeal shock wave (CPT code 50590) nationally is $821.67, while the Hospital Outpatient Payment Schedule rate is $3,647.00. The reimbursement rate for lithotripsy procedures dropped around 21% due to Medicare's correction of an erroneous payment rate.[4] CPT code 50590 (fragmenting of kidney stone) was set at a national average of $2,102.29 upon its November 2011 release. On April 24, 2012 however, CMS adjusted the payment rate to $1,665.59, a reduction of $436.70 or 20.77%. The rate is retroactive to January 1, 2012.

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[1] http://www.aksm.com/Benefits/Final.Physician%20Ownership%20White%20Paper%20Oct%202010.pdf
[2] https://www.federalregister.gov/articles/2011/11/30/2011-28612/medicare-and-medicaid-programs-hospital-outpatient-prospective-payment-ambulatory-surgical-center
[3] http://m.reedsmith.com/files/Publication/81b278ae-4de8-4327-bafb-6090195a6464/Presentation/PublicationAttachment/e76ea9e2-e3a8-4766-aa07-a78e4feb4062/hc0215.pdf
[4] http://www.outpatientsurgery.net/news/2012/05/1-436-70-Less-for-Lithotripsy

MICHIGAN CON COMMISSION MEETING

Outline of Testimony

January 29, 2013

A. Credibility / Who we are

   a. Ted Amland – VP of Operations for AKSM, the management company for Greater Michigan Lithotripsy (GML), with more than 25 years of Lithotripsy experience in field service, technical support, training, operations, logistics and management. AKSM provides urology services in 24 states, operates 60 Litho units and performs approximately 130,000 treatments annually, of which 30,000 are UESWL.

   b. AKSM & GML formed a partnership in January, 2005 and have performed nearly 24,000 treatments in Michigan since then on three mobile lithotripsy routes.

B. Our concern is that the number of cases required to expand the number of lithotripsy units on a mobile route is excessive and results in insufficient access to this service for the residents of Michigan.

   i. GML currently serves (23) facilities and we are at optimum capacity on all three (3) of our routes.

   ii. Our physicians **need** more access to our equipment so that patients can be treated in a timely manner and forego more invasive and costly alternative procedures.

C. The current standards require 1,800 procedures annually in order to expand an existing route

   a. With approximately 254 business days in a year, this would require treating approximately 7 cases each day

D. To illustrate how this would impact service to physicians and patients, let's look at GML Route 165

a. This route encompasses over 9,000 square miles and provides UESWL to (6) hospitals and (1) surgery center in western Michigan.

E. In order to expand this route, the following actions would occur

a. Treatment schedule changed to 6am – 8pm daily

b. Additional technical and transport staff (14 hour DOT rule)

c. Increased burden on:

i. Patients – fasting, work schedule

ii. Physicians – office hours, OR block time

iii. Hospital staff – Litho block time change, anesthesia demand

d. Increased costs will cause higher deductibles and insurance payments

e. Operating at this rate causes:

i. Higher than normal equipment failures

ii. Doesn't account for any delays in scheduling, hospital support, required ancillary procedures such as cystoscopy

iii. Increase human error due to higher stress levels

f. We're proud of our record in this state of no adverse incidents, and we want to keep it that way.

F. In our experience in other states, we have found that when a single mobile unit exceeds 1,000 procedures per year, it's time to start planning to add a second machine to that route. Therefore, we respectfully request that the CON Commission establish a Workgroup to consider lowering the CON requirement for expanding a mobile lithotripsy route.

Attachment E

MDCH Mobile Lithotripsy Route 165
AKSM Unit 147

SPECTRUM HEALTH

Furthest Route:
Spectrum Health Reed City-
Bronson Battle Creek
151 Miles, 2 hrs. 15 mins.

A	Spectrum Health Reed City Hospital	Reed City
B	North Ottawa Community Hospital	Grand Haven
C	Spectrum Health Butterworth Hospital	Grand Rapids
D	Healthcare Midwest Surgery Center	Kalamazoo
E	Bronson Methodist Hospital	Kalamazoo
F	Borgess Medical Center	Kalamazoo
G	Bronson Battle Creek Hospital	Battle Creek

Source: Certificate of Need

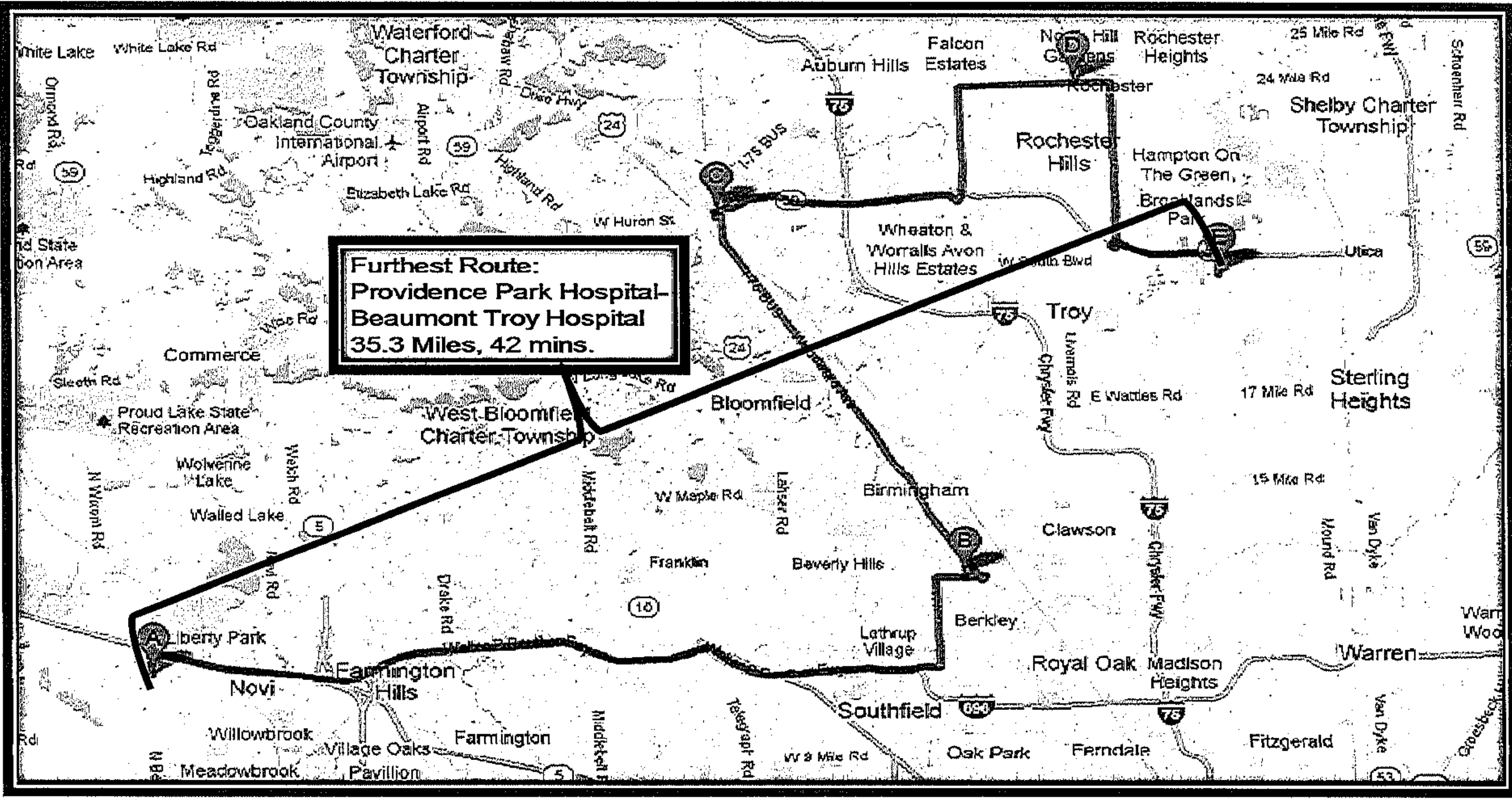
Prepared By: Cody Nihem
M:\Srd\Common\MapInfo\FY13\Lithotripsy Route CN 1-21-13\

1/28/2013

Attachment E

MDCH Mobile Lithotripsy Route 164
AKSM Unit 146

SPECTRUM HEALTH



A	Providence Park Hospital	Novi
B	William Beaumont Hospital	Royal Oak
C	McLaren Osteopathic Hospital	Pontiac
D	Crittenton Hospital	Rochester
E	William Beaumont Hospital	Troy

Source: Certificate of Need

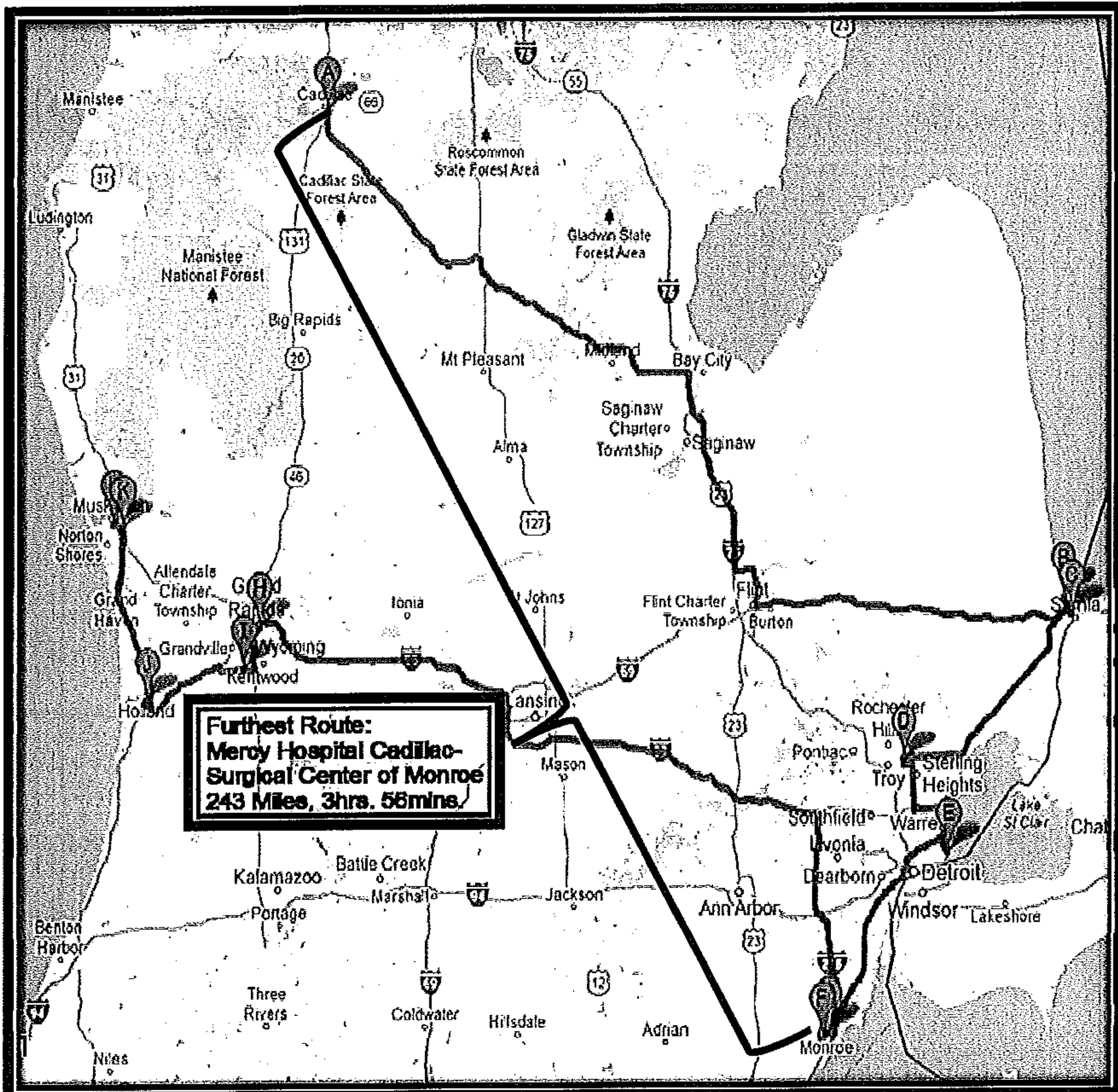
Prepared By: Cody Nihem
M:\Srd\Common\MapInfo\FY13\Lithotripsy Route CN 1-21-13\

1/28/2013

Attachment E

SPECTRUM HEALTH

MDCH Mobile Lithotripsy Route 167
AKSM Unit 148



A	Mercy Hospital	Cadillac
B	Lakeshore Surgery Center	Fort Gratiot
C	Port Huron Hospital	Port Huron
D	William Beaumont Hospital	Troy
E	William Beaumont Hospital	Grosse Pointe
F	Surgical Institute of Monroe	Monroe
G	Mercy Memorial Hospital	Monroe
H	St. Mary's Healthcare	Grand Rapids
I	Metro Health Hospital	Byron Center
J	Holland Hospital	Holland
K	Muskegon Surgery Center	Muskegon
L	Mercy Health Partners-Hackley	Muskegon

MDCH Recommendations for CON Standards Scheduled for 2013 Review

Neonatal Intensive Care Services/Beds (NICU)			
Should the covered service continue to be regulated?	Yes.		
Identified Issues	**Issues Recommended for Review**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Evaluate the need for regulation of levels of care for newborns	Yes	Formation of a workgroup	MDCH has been provided compelling evidence that perinatal Level II care needs further clarification. Further, national guidelines have changed for all levels of perinatal care.
Review the need to add a provision to retrospectively change a hospital's perinatal level of care	No	No action on this issue at this time	Hospitals cannot be retrospectively required to change designation.
Consider decreasing the number of live births to 1,500 to initiate service	No	No action on this issue at this time	Bed need figures show no issue of access.
Department recommended technical/format changes to the Standards	Yes	The Department will draft the technical changes	Modified for consistency with other CON review standards.

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 2013.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 10 - 24, 2012. Testimony was received from five (5) organizations and is summarized as follows:

1. *Robert Meeker, Spectrum Health*
   - Supports continued regulation of the CON review Standards for NICU Services and recommends no revisions at this time.

2. *Patrick O' Donovan, Beaumont Health System*
   - Supports continued regulation of the CON review Standards for NICU Services and recommends no revisions at this time.

3. *Rose Mary Asman, The Division of Family and Community Health (DFCH)*
   - Supports the regulation of this service.
   - Recommends adding requirements to the standards to regulate beds for Level I (basic nursery) and Level II (special care nursery) according to the Level of Care Guidelines released August 27, 2012 by the American Academy of Pediatrics [AAP]/ American Congress of Obstetricians and Gynecologists [ACOG].
   - Recommends creating a provision to retrospectively change a hospital's perinatal level of care designation. Hospitals cannot and should not be grandfathered into an old system.

4. *Sean Gehle, St. John Providence Health System*
   - Supports continued regulation of NICU services and recommend no changes to the standards at this time.

5. *Karen Kippen, Henry Ford Health System*
   - Supports continued regulation of NICU services.
   - Recommends considering lowering the initiation volume to a minimum of 1,500 births per year in the most recent 3 years in a metropolitan statistical area county.

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 states that have CON. The Department recommends continued regulation of NICU services.

Bed Need and Live Births

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**
2008	119,183	2,143	**569**
2009	117,309	1,952	**553**
2010	114,717	1,897	**507**
2011	114,159	1,827	**[1]TBD**
Percentage of change between 2007 and 2011	**4.22% Decrease**	**14.75% Decrease**	**12.23% Decrease**

Since 2007, there has been a 4.22% decrease in live births, a 14.75% decrease in VLBW births. The result is a 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***	**2011 Average Occupancy per HSA****
HSA 1	358	358	289	(69)	**67.8%**
HSA 2	33	33	30	(3)	**86.2%**
HSA 3	45	45	43	(2)	**83.2%**
HSA 4	82	87	71	(16)	**90.5%**
HSA 5	44	44	33	(11)	**65.8%**
HSA 6	40	40	27	(13)	**80.6%**
HSA 7	12	12	8	(4)	**40.4%**
HSA 8	10	10	6	(4)	**92.8%**
Statewide Totals	**624**	**629**	**507**	**(122)**	**73.6%**

* Data from the January 2, 2013 NICU Bed Inventory.
**Data from the 2011 Annual Survey Data.

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 122 beds. No new programs would be allowed to open in any HSA. It is recommended that no action be taken on this issue.

<u>Addition of Regulation for Level I and II Nurseries</u>

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[1] This number shall be calculated when the 2011 total births and VLBW numbers are separated by county, this data is obtained from Vital Records.

The Department received one recommendation to review the need for bed designation for Level I and Level II nurseries within the NICU. CON already provides the type of service needed for Level III nurseries. MDCH recommends adding requirements to the NICU standards for regulation for Level II nurseries. This addition to the NICU standards supports the CON Commission's goal of ensuring quality of care.

MDCH Staff Recommendations

The Department recommends the formation of a workgroup to develop language to include CON requirements for Level II nurseries and review the national guidelines for all levels of perinatal care.

Public Comment
CON Special Commission Meeting
January 29, 2013

Thank you for the opportunity to provide Public Comment on behalf of the Division of Family & Community Health (DFCH) at Michigan Department of Community Health.

DFCH Recommendations Regarding Neonatal Intensive Care Services/Beds (NICU)

The Division of Family and Community Health is recommending changes in the Certificate of Need NICU bed standards based on national Level of Care Guidelines for birth hospitals from American Academy of Pediatrics (AAP) and the American Congress of Obstetrics and Gynecologists (ACOG).

Background
Part of Gov. Snyder's Dashboard includes infant mortality. The State of Michigan's Infant Mortality Reduction Plan was released in August 2012. There are eight strategies. The first strategy is to implement a regional perinatal system. A statewide perinatal coordinated system encompasses system work that involves multiple aspects across the lifespan continuum, including preconception care, prenatal care, care of the high risk mother, ***levels of care of birth hospitals,*** pre and inter-hospital transfers, NICU follow up, coordination and collaboration with community agencies, and local health departments. Pregnant women and babies are more likely to deliver in an appropriate hospital setting and receive appropriate services to meet their needs. A statewide coordinated perinatal system of care will improve infant morbidity, mortality and reduce cost of care for high-need infants.

Levels of Care for Birth Hospitals
In 2009, Michigan Level of Care Guidelines[1.] was published based on recommendations of AAP/ACOG and key perinatal leaders in the State of Michigan. Nationally, new Levels of Care Guidelines were published in October 2012 by the AAP and ACOG[2.]. The new levels of care include Level I (basic OB/nursery care), Level II (special care OB/nursery care), and Level III and Level IV which are NICU levels.

Regulation of Level of Care Guidelines
In visits to State of Michigan NICUs, we have noted three "models" of NICU bed utilization. Fifty percent of NICUs have "licensed" and "unlicensed beds" in their NICU unit. Some NICUs have NICU beds on one unit and unlicensed Special Care Nursery (Level II) beds on a separate unit. The third model is that the hospital has the same amount of NICU beds that CON authorizes.

There is NO regulation for Level II/Special Care Nursery beds in the state. There is considerable variation in the level of care provided in these Special Care Nursery beds (age of gestation, length of time on ventilators, specialty physician varies). "Teeth" are needed to enforce the recommendations for Level of Care Guidelines for the safety of infant care across the state.

It is also recommended to create a provision to retrospectively change a hospital's perinatal level of care designation. Hospitals should not be grandfathered into an "old system.".

Why CON?
CON already provides the type of service needed for NICU nurseries through the NICU bed standards. An addendum for NICU standards seems logical for Level II nursery regulation. This would provide a service for hospitals.

Designation, Verification, Certification

Part of the perinatal regionalization process to implement a designation, verification and certification for the Levels of Care of birth hospitals. A process was recommended by a Workgroup which convened last year (included specific application, application acceptance, site verification process, peer review teams, denial, appeal and corrective action). The workgroup made a recommendation for CON to be involved in the process of designation of Levels of Care among birth hospitals. All hospitals would apply for their desired designation. If the level desired is regulated by CON, the hospital must meet all the requirements in the CON Standards.

Summary

DFCH commends the CON Commissioners and the CON Staff for their diligent efforts to maintain a strong, vibrant CON program. DFCH looks forward to working with CON to assure the delivery of high quality, safe and effective perinatal care across the state.

If you have more questions, I would be happy to come in and provide a presentation.

Thank you for your consideration.

References

[1.] Michigan Department of Community Health (2009) *Perinatal Regionalization: Implications for Michigan.* Available: http://www.michigan.gov/documents/mdch/1116_04_01_09_274917_7.pdf

[2.] Committee on Fetus and Newborn (2012). Policy Statement: Levels of Neonatal Care. *Pediatrics 130,* pp 587-597 DOI: 10.1542/peds.2012-1999

Brief Overview of Perinatal Level of Care Guidelines

Basic Level [*Level I (Basic)]*

- Community-Based Maternal-Newborn Service
- ≥ 35 weeks gestation
- Care if uncomplicated births

Special Care Nursery – [*Level II A-b (Subspecialty])*

There is NO REGULATION for THESE BEDS

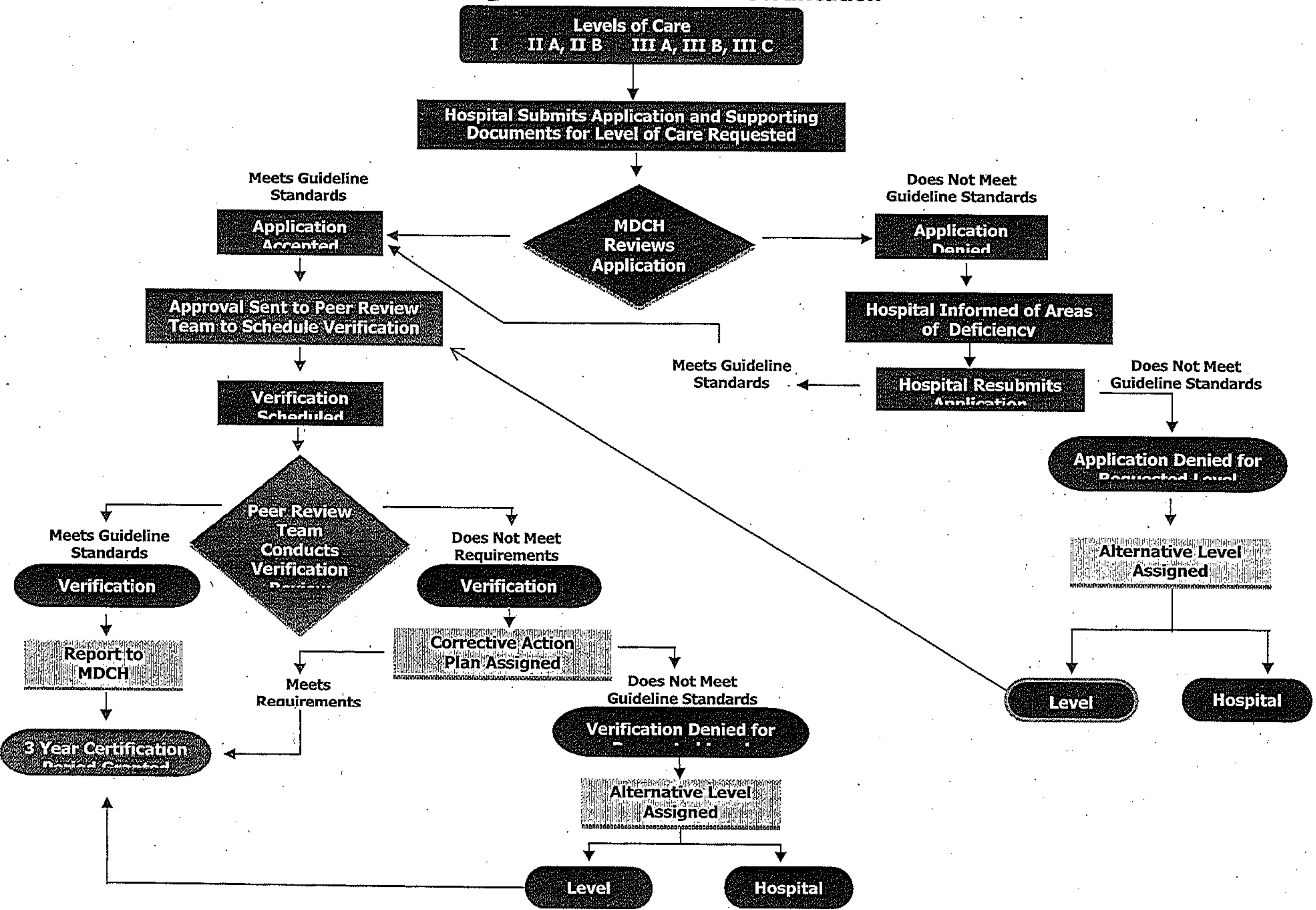
- Community-Based Maternal-Newborn Service with a Special Care Nursery
- > 32 weeks gestation
- > 1,500 gm
- Uncomplicated preterm infant
- CPAP and mechanical ventilation for less than 24 hours
- Stabilization of sick newborn infants until transfer only
- No surgery

Neonatal Intensive Care Unit (NICU)

All 3 of these levels follow the CON NICU Bed Schedule

- *Level IIIA (Subspecialty)*
  - Perinatal Care Center and Neonatal Intensive Care Unit
  - > 28 weeks gestation and weight > 1,000 gm
  - At least 15 VLBW infants born per year
  - CPAP and conventional mechanical ventilation
  - Minor surgery, central line and hernia repair
  - Women without significant co-morbidities
- *Level III B (Subspecialty)*
  - Perinatal Care Center and Neonatal Intensive Care Unit with Neonatal Subspecialty Service
  - < 28 weeks gestation and weight < 1,000 gms or with complex illnesses
  - At least 70 VLBW infants per year
  - High frequency ventilation, Inhaled nitric oxide
  - Pediatric surgery (except cardiac)
  - All maternal conditions
- *Level III C (Subspecialty)*
  - *Perinatal Care Center or Freestanding Pediatric Hospital with Neonatal Subspecialty Service*
  - *< 28 weeks gestation and weight < 1,000 gms or with complex illnesses*
  - *At least 70 VLBW infants per year*
  - *Infants with ECMO or open cardiac surgery*
  - *All maternal conditions*

DRAFT



MDCH Recommendations for CON Standards Scheduled for 2013 Review

Nursing Home and Hospital Long-Term-Care Unit Beds (NH) Standards			
Should the covered service continue to be regulated?	Yes.		
Identified Issues	**Issues Recommended for Review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Examine the Comparative Review Criteria, to view efficiency	Yes	Formation of a work group	Intent is to increase quality of care, add to the project delivery requirements.
Modify the Relocation criteria in Section 7	Yes	Formation of a work group	As the standards are now, it limits the Department's flexibility. NH are limited to relocating no more than 50% of its beds.
Modify replacement language – eliminating Section 8 (3)(c)(i)	Yes	Formation of a work group	Per part 333.22229, replacement beds in a NH are not subject to comparative review if it is within a 2-mile radius. Strike the language that states between 2-3 miles.
Examine the number of Special Pool Hospice Beds	No	Formation of a work group	There has been activity within the last 2 years so no beds exist to place in the pool.
Department recommended technical and format changes to the Standards	Yes	The Department will draft the technical changes	
Modify the renewal of lease definition	Yes	The Department will draft the proposed language	
Modify the acquisition language	Yes	The Department will draft the proposed language	The intent is to clarify and require evidence of the agreement to the proposed change of ownership.

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 2013.

Public Hearing Testimony

The Department held a Public Comment period to receive testimony regarding the Standards on October 10 - 24 2012. Testimony was received from (thirteen) 13 organizations and is summarized as follows:

1. *David Herbel, Aging Services of Michigan*
   - Recommends formation of a Standard Advisory Committee (SAC) specifically tasked to address the costs, quality and access issues facing Michigan's long term community.
   - Proposes a Regional Needs Assessment be conducted within targeted areas of Michigan prior to the approval or construction of "new" beds. Analysis should include the expansion alternative LTC programs and services that are funded within the targeted areas rather than the lengthier and more costly 30-year commitment to "new" nursing home beds.
   - Recommends that Class I nursing homes with high occupancy rates should be allowed to expand at the same rate as Class III. This would address consumer preferences and ultimately overall performance.
   - Recommends that applicants be ineligible to obtain beds from the bed pool for an existing facility or the same licensee if it is currently subject to a Medicaid "non-available" bed plan.

2. *Linda Beushausen, Hospice at Home; Hospice and Palliative Care Assoc. of Michigan*
   - Request an increase of 60-130 beds allocated to the Special Pool for Hospice, doubling the size and number of counties that could benefit from the pool.
   - Due to federal regulations, Medicaid can only provide room and board reimbursement for hospice patients if they are in a licensed nursing home or hospital bed. Michigan's Medicaid population has continued to increase, placing a burden upon hospice providers operating without nursing home licensure.
   - In addition, recommends that the maximum number of beds allowed by a facility be 20 beds, rather than 30, to ensure the greatest geographic access and financial viability.

3. *Lisa Ashley, Hospice and Palliative Care Assoc. of Michigan*
   - Currently there are 130 beds in the pool (all have been granted to CON applicants), resulting in only 9 facilities being able to obtain beds from it. This means that patients in only 9 counties, out of 83, have access to these beds. Request an increase of 60-130 beds allocated to the Special Pool for Hospice, doubling the size and number of counties that could benefit from the pool.
   - Due to federal regulations, Medicaid can only provide room and board reimbursement for hospice patients if they are in a licensed nursing home or hospital bed. Michigan's

Medicaid population has continued to increase, placing a burden upon hospice providers operating without nursing home licensure.
- In addition, recommends that the maximum number of beds allowed by a facility be 20 beds, rather than 30, to ensure the greatest geographic access and financial viability.

4. *Melissa Cupp, Wiener Assoc.*
   - Recommends modifying the definition of "relocation of existing nursing home/HLTCU beds" to mean a change in the location of existing nursing home /HLTCU beds from a licensed site to a different EXISTING licensed NURSING HOME/HLTCU site within the planning area.
   - Recommends modifying Section 15(2) to include projects replacing beds under the new design model within the planning area to the list of projects that do not require comparative review.
   - Suggests the Commission consider removing the limitation that only 50% of facilities beds be relocated to another existing licensed nursing home. This has created hurdles to moving beds out of older facilities to combine beds together that would have resulted in positive projects.

5. *Amy Barkholz, Michigan Health & Hospital Assoc.*
   - Proposes an increase of 130 beds allocated to the Special Pool for Hospice, doubling the size and number of counties that could benefit from the pool.
   - In addition, recommends that the maximum number of beds allowed by a facility be 20 beds, rather than 30, to ensure the greatest geographic access and financial viability.

6. *Sean Gehle, Genesys Health Systems*
   - Supports continued regulation of Nursing Home and HLTCU Beds.
   - Proposes expanding the replacement & relocation zone beyond the current mile radius limitation.

7. *Sarah Slocum, Michigan Long Term Care Ombudsman Program*
   - Proposes including MI Choice need and supply in calculations of regional or county LTC needs, not just NH beds.
   - Recommends deducting points from applicants who have failed to meet their project delivery requirements.
   - Recommends granting additional points within comparative review for proposals including 100% dual Medicare/Medicaid certification.
   - In addition, reward applicants' additional points for quality improvement initiatives such as: reduced pressure sore rate, reduced use of restraints, and complete adoption of consistent assignment of direct care staff.
   - Retain item (5) and delete item (7) on page 15 of the standards.
   - Additionally on page 15, items (10) reduce the number of beds from 150 to 80. Smaller facilities have been found to provide person-centered.
   - Increase the points awarded for wireless nursing call systems, wireless internet, and computer stations/internet cafes for residents from 1 point to 5 points each.

8. *Cean Eppelheimer, Michigan Alliance for Person Centered Communities*

- Recommends retaining the culture change provisions within the comparative review sections of the standards. Person-centered care initiatives lead to both quality of life and clinical outcomes.

9. *Lisa Rosenthal, HCR ManorCare*
   - Supports revising the Comparative Review Criteria recommending the following changes:
   - Sections 4 & 5- Support updating the Nursing Home bed need projections using base year data from 2010.
   - Section 6 (1)(d)(ii)(A)– recommend that nursing homes that meet the occupancy threshold, be permitted to add 10 beds or 10% of licensed capacity every two years, and not be tied to the planning area occupancy.
   - Recommends that the requirement for outstanding obligations for Quality Assurance Program (QAAP) or Civil Monetary Penalties (CMP) change to have due dates at least 60 days prior to the application filing so that the applicant is considered current in payment.
   - Recommends that the seven year restriction be deleted from Section 7.
   - Section 10(2) - revise points awarded so as not to penalize nursing homes that focus on post-acute care.
   - Section 10(15) - Increase points awarded to quality post-acute providers, in recognition of electronic technology capabilities within nursing homes.
   - Recommend adding new comparative review criteria to award points to nursing homes that demonstrate initiatives aimed at decreasing re-hospitalization.
   - Section 10(4) - Recommend increasing point deduction for poor quality nursing homes to 25 points, to demonstrate track record of consistent quality nursing home services.
   - Section 10 (5) Culture Change- Update the approved Culture Change list as it is outdated and should reflect newer initiatives such as post-acute care, use of innovative technology, successful discharge outcomes that avoid re-hospitalization.
   - Sections 10(6) and 10(11)- Recommends increasing points awarded for applicants who provide cash for project funding and audited financial statements as a demonstration of financial strength.
   - Section 10 (7)- Eliminate the five points awarded for sprinkling of the proposed nursing home space to be constructed as this is already required by Medicare/Medicaid.

10. *Pat Anderson, Health Care Assoc. of Michigan (HCAM)*
    - Supports continued CON regulation.
    - HCAM strongly recommends that the current Bed Need be updated to reflect the 2010 census data to provide for the changes in demographics.
    - Recommends an exception to the number of beds approved for high occupancy be consistent within both Section 6 (vi) (d) (ii) and (vi) (iii) (B) to reflect 92%.
    - Review and possibly eliminate the relocation language specifically as it relates to 50% of the beds to be relocated and then once every 7 years.
    - Recommends that total replacement facilities on their current site or within the planning area, be required to only file an LOI which would be granted a waiver from the full CON application process.
    - Recommends that the renewal of an existing lease with the same parties be granted a waiver under CON upon the filing of an LOI.

- Recommends the following changes to Section 10 for comparative review: no points for sprinklers as it is a federal mandate as of August 13, 2013; review changes in Medicaid participation providers that are serving sub-acute care needs; downsizing wards, and recognition of technology utilized in long-termed care.
- Recommends reviewing addendum for Special Pop Groups.
- Recommends that QAAP and CMP language state that these obligations have due dates at least 60 days prior to the application filing so that the applicant is considered current in payment.
- Proposes that the administrative rule process for a change in location of the nursing home after approval has been granted. Amend language to read a new location can be granted under the same CON to build, and if the applicant demonstrates the new site is within the planning area and the 3-mile rule is available, then a new CON is not required.
- Recommends reviewing and changing the average number of "D" citations for the period from July 2011 to March 2012, the data appears to be wrong and should be corrected.

11. *David G. Stobb, Ciena Healthcare*
    - Recommends simplifying the CON Standards to allow healthcare providers the flexibility to build, replace, and relocate aging facilities to meet the demands of the skilled nursing consumer.
    - Recommends removing the concept of the replacement zone from the NH Standards, which limits the ability to build or replace nursing homes in areas where there is a demand within the county.
    - Recommends deleting the limitation within Section 2 (d)(i).
    - Recommends removal of the 50% and 7 year restrictions as they apply to the relocation of beds.
    - Proposes the allowance for providers to "bank" the beds they desire to remove from an existing facility for a period of 2-3 years so they can decide what to do with the beds.
    - Recommends eliminating the language that states new acquisitions that require a CON must participate in a quality improvement program and provide annual reporting to the state and ombudsman.
    - Recommends that renewal leases be exempted from the CON standards.
    - Proposes removing the 5 point advantage that an existing provider has with a cultural change program over a new applicant who will implement a cultural change model.
    - Proposes increasing the points awarded for use of technology for a project.
    - Recommends removing the category that awards points for a project accessible to public transportation.

12. *J. Mark Greene, Extendicare Health Services*

    - Recommends updating Section 2 (1)(d) to state the most current survey.
    - Update the bed need to reflect 2010 census statistics.
    - Proposes eliminating the 14% or 5 maximum that may penalize certain larger providers.
    - Exclude QAAP, and simply state "If no pay, no play."

- Eliminate or adjust the relocation language specifically, the 50% of beds and once every 7 years.
- Requests that total replacement facilities be required to only file an LOI which would be granted a waiver from the full CON application process.
- Requests that a provider with a larger facility be able to split the facility into two smaller centers serving the same planning area or to combine the two older facilities into a single structure.
- Proposes that the comparative review sections within the standards be reviewed and adjusted to meet the changing landscape of long-term care services.

13. *Patrick O' Donovan, Beaumont Health System*
    - Supports the continued regulation of nursing home and HLTCU beds and services.

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.

MDCH Staff Recommendations

The Department recommends the Commission delegate to the Department formation of a workgroup to address all of the above stated issues, especially modification of the relocation and replacement criteria for NH beds. The Department recommends technical/editorial modifications to the Standards to update language and revise format. The Department recommends clarifying the definition of "acquisition of an existing nursing home/HLTCU" and is prepared to address this issue within a workgroup setting.

The Department received a recommendation to modify the relocation criteria in Section 7 to eliminate the criteria which restricts the applicant to only being able to move 50% of the beds for licensed nursing home beds to another facility. The Department recommends removing this limiting language so that it is the same as the HLTCU that do not have this restriction.

The Department also recommends removing the replacement language within Section 8(3)(c)(i). This provision is preventing new nursing homes from being built and was originally drafted to be a pilot program in 2008. The language is no longer necessary as the original pilot programs are all CON approved.

The Department did receive testimony proposing an increase of 130 beds allocated to the Special Pool for Hospice, doubling the size and number of counties that could benefit from the pool. 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 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).

Section 3(1)(c) requires that six 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 October 2010 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	162	130	0
Unmet Bed Need*	320	400	0	179
Most recent application period with CON activity since October, 2010	October 2011	October 2012	June 2012	June 2012

*Data from the January 2, 2013 Bed Inventory

Due to activity in all special population groups, the Standards dictate that no reallocation can transpire at this time.

Certificate of Need Issues

Hello I am Pat Anderson Executive Vice President for the Health Care Association of Michigan. Thank you for allowing HCAM who represents 295 of the 440 skilled nursing and rehabilitation facilities across the state to testify in support of calling a SAC or workgroup to review the Standards for Nursing Facilities and Hospital Long Term Care Units. Allow me to briefly highlight the issues HCAM believes are in need of modifications.

Primary Concerns:

- Section 3 and 4 - Updating the bed need by planning area to incorporate the population data gathered in the 2010 census.
- Section 7 - Relocation of beds provision reviewed and changed to provide the flexibility needed in today's long term care environment.
- Section 8 – Replacement facilities should be encouraged and supported to upgrade our aging facilities and provide modern physical plants to meet the care needs of the residents. Including the combining of two aged facilities into one new structure without requiring two separate buildings. Replacement facilities should be allowed to file a Letter of Intent and be granted a waiver.
- Section 9 – Renewal of existing lease without a new owner should not require full CON but just a Letter of Intent with a waiver granted
- Section 10 – Comparative review standards need major revamping to provide a clear difference between applicants including recognizing new technology and deleting federal mandates such as the sprinklering requirement.
- Other: Allow a change of site for an existing CON when a change to a new location would provide the opportunity to enhance the care delivery for those needing these health care services.
- Other: Various technical changes and a correction of the documentation regarding the average citations as used within the standards.

Respectfully Submitted,
Patricia Anderson
Health Care Association of Michigan
January 29, 2013