

**MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS)
CERTIFICATE OF NEED (CON) COMMISSION MEETING**

Thursday, January 28, 2016

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

APPROVED MINUTES

I. Call to Order & Introductions

Chairperson Keshishian called the meeting to order at 9:35 a.m.

A. Members Present:

Denise Brooks-Williams
James B. Falahee, Jr., JD
Robert Hughes
Marc Keshishian, MD, Chairperson
Thomas Mittelbrun (participated via phone)
Suresh Mukherji, MD, Vice- Chairperson
Luis Tomatis, MD

B. Members Absent:

Gail J. Clarkson, RN
Kathleen Cowling, DO
Jessica Kochin
Gay L. Landstrom, RN

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Health and Human Services Staff Present:

Tulika Bhattacharya
Amber Myers
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Brooks-Williams, seconded by Commissioner Falahee, to approve the agenda as presented. Motion carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of September 24, 2015

Motion by Commissioner Tomatis, seconded by Commissioner Mukherji, to approved the minutes as presented. Motion carried.

V. Air Ambulance (AA) Services – October 9, 2015 Public Comment Period Summary & Report

Ms. Rogers gave an overview of the public comment period summary and the Department's recommendations (see Attachment A).

A. Public Comment

1. Dennis McCafferty, Economic Alliance of Michigan (EAM)

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Mukherji, seconded by Commissioner Hughes to accept the Department's recommendation as presented. Motion carried in a vote of 6- Yes, 0- No, and 0- Abstained.

VI. Computed Tomography (CT) Scanner Services – October 9, 2015 Public Comment Period Summary & Report

Ms. Rogers gave an overview of the public comment period summary and the Department's recommendations (see Attachment B).

A. Public Comment

1. Melissa Cupp, representing Michigan Dental Association (MDA) (see Attachment C)
2. Dennis McCafferty, EAM

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Hughes to accept the Department's recommendation as presented. Motion carried in a vote of 6- Yes, 0- No, and 0- Abstained.

VII. Nursing Home and Hospital Long-Term-Care Unit (HLTCU) Beds – October 9, 2015 Public Comment Period Summary & Report

Ms. Rogers gave an overview of the public comment period summary and the Department's recommendations (see Attachment D).

A. Public Comment

1. Pat Anderson, Health Care Association of Michigan (HCAM) (see Attachment E)

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner Mukherji to accept the Department's recommendation as presented. Motion failed in a vote of 5- Yes, 1- No, and 0- Abstained.

Motion by Commissioner Falahee, seconded by Commissioner Tomatis to appoint a Standard Advisory Committee (SAC), delegate development and approval of the charge, based on the Department's recommendations, and seating of the SAC, to the Chairperson of the Commission. If a SAC cannot be seated after one attempt, then a workgroup will review the Department's recommendations. Motion carried in a vote of 6 - Yes, 0 - No, and 0 - Abstained.

VIII. Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services – October 9, 2015 Public Comment Period Summary & Report

Ms. Rogers gave an overview of the public comment period summary and the Department's recommendations (see Attachment F).

A. Public Comment

1. Colleen Barry, MDHHS
2. Barbara Bressack, Henry Ford Health System

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Mukherji to accept the Department's recommendation as presented. Motion carried in a vote of 6- Yes, 0- No, and 0- Abstained.

IX. Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services – October 9, 2015 Public Comment Period Summary & Report

Ms. Rogers gave an overview of the public comment period summary and the Department's recommendations (see Attachment G).

A. Public Comment

1. Jorgen Madsen, Great Lakes Lithotripsy
2. Bob Meeker, Greater Michigan Lithotripsy
3. Steve Szelag, University of Michigan
4. William Roberts, MD, University of Michigan

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Tomatis to continue regulation of UESWL services and have the Department draft technical edits as stated from the University of Michigan and bring back to the Commission at a future meeting. Motion failed in a vote of 4- Yes, 2- No, and 0- Abstained.

Motion by Commissioner Mukherji, seconded by Commissioner Hughes to appoint a SAC to consider deregulation of UESWL services and delegate development and approval of the charge and seating of the SAC to the Chairperson of the Commission. Motion carried in a vote of 6 - Yes, 0 - No, and 0 - Abstained.

X. Public Comment

None.

XI. Review of Commission Work Plan

Ms. Rogers gave an overview of the Commissions future work plan to include the decisions made at today's meeting (see Attachment H).

A. Commission Discussion

None.

B. Commission Action

Motion by Commissioner Mukherji, seconded by Commissioner Tomatis, to accept the work plan as presented. Motion Carried in a vote of 6 - Yes, 0 - No, and 0 - Abstained.

XII. Future Meeting Dates – March 16, 2016, June 15, 2016, September 21, 2016, & December 7, 2016

XIII. Adjournment

Motion by Commissioner Landstrom, seconded by Commissioner Mittelbrun, to adjourn the meeting at 11:09 a.m. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

MDHHS Recommendations for CON Standards Scheduled for 2016 Review

Air Ambulance (AA) Services			
Department Recommendation: Air Ambulance services should continue to be regulated until the Department's Emergency Medical Services Licensing can update its rules to include Air Ambulance specific requirements. This is expected to take place in 2016.			
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, when the EMS Licensing rules are updated.	Continue regulation and review the Air Ambulance Licensure rules once they are available. At that time, the Commission should consider deregulation of Air Ambulance Services.	

MDHHS 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 2016.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 9 - 23, 2015. Testimony was received from six (6) organizations and is summarized as follows:

1.) **Steven Szelag on behalf of T. Anthony Denton, University of Michigan Health System (UMHS)**

- Supports continued regulation of AA Services through CON program.
- States that the Emergency Medical Services (EMS) Section initiated a rule-making process to update their program to address quality in AA services, but feels until the process is complete and new rules are in effect with EMS regulations, CON Standards for AA Services should remain in effect.

2.) Dennis McCafferty, Economic Alliance for Michigan (EAM)

- States that in 2014 when the standard was reviewed, the consensus of the “workgroup” was that the patient safety and quality provision for AA Services only existed within the CON Standards.
- States that until patient safety and quality provisions are replicated in other State regulations of emergency transportation services they are reluctant to support de-regulation.
- Further states that it is difficult to submit comments on AA Services when no survey reports have been posted for 2014. (*Department Note: Survey reports for both 2013 and 2014 have been posted on the CON web site as of 11/19/15.*)

3.) Kelly Ann Hekler on behalf of Kenneth P. Cummings, Michigan Assoc. of Ambulance Services (MAAS)

- Supports continued regulation of AA Services.
- States that the EMS Section initiated a rule-making process to update their program to address quality in AA services, but feels until the process is complete and new rules are in effect with EMS regulations, CON Standards for AA Services should remain in effect.
- Further states that CON has effectively safeguarded patient safety and avoided unnecessary healthcare costs in Michigan by protecting the State from the proliferation of helicopters that has occurred in many other states.

4.) Patrick O’ Donovan, Beaumont Health

- Supports continued regulation of AA Services and recommends no changes at this time.

5.) Sean Gehle, Ascension Michigan

- Supports continued regulation of AA Services and recommends no changes at this time.

6.) Barbara Bressick, Henry Ford Health System (HFHS)

- Supports continued regulation of AA Services and recommends no changes at this time.
- States that the EMS Section initiated a rule-making process to update their program to address quality in AA services, but feels until the process is complete and new rules are in effect with EMS regulations, CON Standards for AA Services should remain in effect.

History of the Covered Service:

The AA Services Standards were reviewed by a CON workgroup in 2013. This workgroup updated the AA Services Standard to be in line with the FAA ruling, which had removed the ability of the States to restrict Air Ambulance services based on need. At its March 18, 2014 CON Commission meeting, the Commission took final action on standards that removed all language regarding need. At this meeting the Commission stated that Air Ambulance Service would remain regulated by CON until the EMS licensing in the

Department of Health and Human Services could update the licensure process to include Air Ambulance specific criteria.

In 2015, the EMS of the Department of Health and Human Services worked with Air Ambulance providers to develop specific criteria into the state licensing administrative rules. The draft is currently being reviewed and is expected to move forward through the state of Michigan rule making process during the 2016 calendar year.

Summary of FAA Exemption:

The US Department of Transportation (US DOT), in attempting to clarify the limits of federal regulation, has indicated that 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.2d at 738.¹

2014 AA Service Data

The 2014 Annual Survey data is the latest available and can be viewed at:

Service Providers http://www.michigan.gov/documents/mdch/Report_150_506633_7.pdf

Additional Services http://www.michigan.gov/documents/mdch/Report_152_506634_7.pdf

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

MDHHS Recommendations for CON Standards Scheduled for 2016 Review

Computed Tomography (CT) Standards			
Department Recommendations: CT should continue to be regulated by CON. The Commission should form a workgroup to make a recommendation regarding the regulation of dental CT scanners.			
Identified Issues	Issue Recommended for Review?	Recommended Course of Action to Review Issues	Other/Comments
Deregulate CT Scanners	No.		
Deregulate Dental CT Scanners	Yes.	Form a Workgroup	
Review project delivery requirements to determine if all requirements are appropriate for freestanding CT scanner services	Yes.	Department form draft language for CON Commission review	Issue identified by CON Evaluation section.
Bring CT standards in line with other CON standards to clarify hospital replacement exemptions	Yes.	Department form draft language for CON Commission review	Issue identified by CON Evaluation section.

MDHHS 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 2016.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 9 - 23, 2015. Testimony was received from four (4) organizations and is summarized as follows:

- 1.) *Steven Szelag on behalf of T. Anthony Denton, University of Michigan Health Systems (UMHS)*
 - UMHS recommends convening an informal workgroup to evaluate the necessity for continued CON regulation of CT scanner services.

- 2.) *Bill Sullivan, Michigan Dental Association*
 - Requests the de-regulation of dental CT scanner services.
 - Cone Beam CT (CBCT) has become the standard of care for dentistry across the nation and dentists still are not able to implement this technology in their offices either at all, or without jumping over significant hurdles put in place by the CON process in Michigan.

- Michigan remains one of only two states still regulating this technology under CON.
- The average CBCT costs less than \$100,000 and is comparable to a panoramic x-ray machine, which any dentist can purchase without a CON. CBCT allows the dentist to view the images taken in third dimension, allowing them to provide better treatment to their patients.

3.) *Patrick O' Donovan, Beaumont Health*

- Supports continued regulation of CT Services and recommends no changes at this time.

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

- Supports continued regulation of CT Services.

Background:

The CT standards were reviewed with a workgroup in 2013. The current effective date of the CT standards is December 22, 2014.

CT Survey Data for 2014:

Annual survey data for 2014 is the latest available and can be found here:

Hospital and Freestanding CT

http://www.michigan.gov/documents/mdch/Report_101_506622_7.pdf

Mobile CT http://www.michigan.gov/documents/mdch/Report_106_506627_7.pdf

Dental CT http://www.michigan.gov/documents/mdch/Report_107_506628_7.pdf

DIST 21 MTG
Cupp Attachment
behalf of MDA



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

January 28, 2016

Dr. Marc Keshishan, M.D.
Chairman
Certificate of Need Commission
Michigan Department of Health and Human Services
201 Townsend, 7th Floor
Lansing, MI 48913

Re: CON Standards for Computed Tomography (CT) Services

Dear Chairman Keshishan,

The Michigan Dental Association (MDA) appreciates you taking the time to consider our request from the October public comment period. Hopefully you have had an opportunity to read our comments and our request to remove Dental CT from CON regulation. We understand that the Department is recommending a workgroup review this request. However, we would suggest that a workgroup is not necessary and ask that the full CON Commission address this issue directly. This request is made with the utmost respect for the process, but history has shown that, despite what seems to be general support for the concept of deregulating the Dental CT, the majority of members of these workgroups/Standards Advisory Committees (SAC) will not vote in support because of concerns of the "slippery slope" and how it might impact other uses of similar technology. As a result, the full CON Commission has never really had the opportunity to discuss and vote on this issue. We believe it is time for them to do so.

Over the past 12 years the MDA has made three attempts through the CON workgroup/SAC process to have the Dental CT removed from CON regulation. Those attempts have involved an enormous amount of time and resources for all involved to prepare for, conduct, and attend the workgroup/SAC meetings. Going down this path again, and expending all of these resources when no facts have changed since the last review, does not seem like the most responsible use of resources.

The information on why it is prudent to deregulate the Dental CT has not changed over the past 12 years. The Dental CT is a safe and effective diagnostic tool (costing less than \$100,000) that is viewed as the standard of care in the dental profession. It is quite similar to the traditional Panoramic X-ray unit utilized across dental offices prior to the inception of the CBCT (technical term for the CT), but allows for 3-D images, improving dentists' ability to treat patients. Michigan is one of only two states that regulate the Dental CT and no compelling information exists to show that this is necessary. In addition, the Dental CT is regulated by the state's Radiation Safety Section to ensure public safety. The full CON Commission can check its past records for the full details.

As a result, the MDA feels that engaging in the workgroup/SAC process is not a wise use of resources. Therefore, we respectfully request that the full CON Commission handle this issue at a future meeting and directly vote on whether or not to remove the Dental CT from CON regulation.

Respectfully,



Bill Sullivan
Director of Government and Insurance Affairs
Michigan Dental Association

CC: Senator Mike Shirkey
Representative Mike Callton

MDHHS Recommendations for CON Standards Scheduled for 2016 Review

Nursing Home and Hospital Long-Term-Care Unit Beds (NH-HLTCU) Standards			
Department Recommendation: Nursing Home and Hospital Long-Term Care Unit Beds should continue to be regulated by CON. The Commission should form a workgroup to provide recommendations regarding the issues outlined below.			
Identified Issues	Issues Recommended for Review?	Recommended Course of Action to Review Issues	Other/Comments
Review the criteria for NH-HLTCU replacements and the relocation of beds	Yes.	Form a workgroup	
Review the criteria concerning lease renewal	Yes.	Form a workgroup	
Review the threshold for high occupancy provisions	Yes.	Form a workgroup	
Review the special population groups in the addendum	Yes.	Form a workgroup	
Review the bed need formula and data sources	Yes.	Form a workgroup	
Review quality metrics to determine if they are up-to-date with national NH-HLTCU trends.	Yes.	Form a workgroup	Issue Identified by CON Evaluation section.
Revise acquisition requirements to reflect a situation where the NH-HLTCU is being acquired by a new entity that does not currently operate a NH-HLTCU.	Yes.	Department to draft language for CON Commission review	Issue Identified by CON Evaluation section.

MDHHS Staff Analysis of the Nursing Home and Hospital Long-Term-Care Unit Beds (NH-HLTCU) 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-HLTCU Standards are scheduled for review in calendar year 2016.

Public Hearing Testimony

The Department held a Public Comment period to receive testimony regarding the Standards on October 9 - 23 2015. Testimony was received from four (4) organizations and is summarized as follows:

1.) *Sean Gehle, Ascension Michigan*

- Supports continued regulation of NH-HLTCU Services and recommends no changes at this time.

2.) *Pat Anderson, Health Care Assoc. of Michigan (HCAM)*

- Recommends a streamlined non-substantive review process for total replacements and renovation regardless of the amount of capital expenditure or location within the planning area. This change would only apply for a replacement that does not include an increase in beds. *[Department Note: This may require an administrative rule change R 325.9205(2)(a)(iv).]*
- Recommends allowing a combined facility project to obtain a single CON to replace all of the beds into a single facility within the planning area. The replacement will result in a single nursing facility with one license.
- Recommends allowing the relocation of beds from an existing nursing facility to a planned new construction, creating a single new facility under a new license within a planning area regardless of the amount of beds.
- Recommends allowing an approved CON where CON construction has not begun to seek an alternative site within the replacement zone when the original site is unavailable due to local ordinances, environmental restrictions, or other restraints.
- Recommends requiring only a waiver be filed when a lease renewal at the existing site does not involve changes to access or quality. The need to review the renewal of an existing lease seems redundant as the original lease has already been reviewed and approved.
- Recommends the application fee be based on the annual value of the leased facility and not the total value of a multi-year lease.
- Recommends Section 22229 should be amended to make it clear that replacement of all or a portion of the existing licensed beds of a nursing facility is never subject to comparative review. *[Department Note: This is would require a statute change.]*
- Recommends that the threshold for high occupancy be consistent and set at 92 percent.
- Recommends the criteria for each special population groups contained in the addendum be reviewed.
- Recommends reviewing the bed need formula and data sources used to determine bed supply.

3.) *Chad Tuttle, Spectrum Health*

- Recommends the creation of a Standard Advisory Committee or workgroup to review the methodology and data sources for bed need supply.
- Recommends changes to ensure CON does not hinder the ability of nursing homes to meet the demands of the aging population.

4.) *Patrick O' Donovan, Beaumont Health*

- Recommends continued regulation under CON and has no recommended changes to these standards.

Background:

The NH-HLTCU Standards regulate a licensed health facility, not a covered clinical service. Therefore, deregulation is not an option.

Nursing Homes were last reviewed by a workgroup in 2014. The effective date of the current standards is March 20, 2015.

2013 Annual Survey Data:

The 2013 Annual Survey data is the latest available and can be viewed at http://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5106-312854--,00.html.



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CON Reforms Related to Skilled Nursing Facilities

Skilled nursing facilities have operated under Michigan's Certificate of Need Program since 1978. The Health Care Association of Michigan supports the current structure which has allowed significant economic development while emphasizing quality of care and serving Michigan's Medicaid population. We offer the recommendations to streamline the process and add greater flexibility for providers and the state, while maintaining the value and focus of CON.

Bed Need Should Accurately Reflect Current Population Needs

HCAM recommends reviewing the formula and data sources used to determine bed supply and need. The most recent proposed bed needs calculation showed decreasing bed need in every county in Michigan. A review of the calculation found inaccurate data and concern with the methodology as a predictor of future bed need.

Requirement for New CON with Location Change

There are instances when an applicant needs to change the location of a nursing facility after a CON application is approved. CON rules require a specific site address for a new facility on an initial application. Sometimes a project is delayed when other applicants file an appeal following a comparative review. During the appeal, which may take years to resolve, the original site of an approved CON may become unavailable and a new location needs to be found. CON only allows a 250 yard radius from the original address for a new location. This distance is too limiting and provides no real ability to find a suitable new location.

HCAM recommends allowing an approved CON where construction has not begun to seek an alternative site within the replacement zone when the original site is unavailable due to local ordinances, environmental restrictions or other restraints. The applicant would need to comply with all other applicable requirements and must make the request within 6 months of final appeal resolution and issuance of the CON.

Relocation of Beds to Meet Consumer Needs

Current CON standards only allow beds to be relocated to an existing nursing facility or to a new design model facility, which is 100 beds or less and not new construction over 100 beds.

HCAM recommends allowing the relocation of beds from an existing nursing facility to a planned new construction, creating a single new facility under a new license within a planning area regardless of the amount of beds.

Exempt Replacement Projects from Potential Comparative Review

Certain replacement projects are subject to "potential comparative review" when the new site is more than 2 miles from the current site. The impact is that these projects can only be filed on comparative review window dates (February 1, June 1 and October 1) – even though they are never actually subject to comparative review. Section 22229 should be amended to make it clear that replacement of all or a portion of the existing licensed beds of a nursing facility is never subject to comparative review.

Amendment to Sec 333.22229(3):

(3) Replacement beds in a nursing home ~~that is located in a nonrural county that are proposed for construction on the original site, on a contiguous site, or within a 2-mile radius of the original site are not subject to comparative review.~~ Replacement beds in a nursing home that is located in a rural county that are proposed for construction on the original site, on a contiguous site, or within the same planning area are not subject to comparative review.

Other Issues to Be Address

Requirements for Approval to Renew Existing Leases

It is unclear why a renewal of a lease arrangement is included in CON similar to an acquisition of an existing facility that would change key staff.

HCAM recommends requiring only a waiver be filed when a lease renewal at the existing site which does not involve changes to access or quality. The need to review the renewal of an existing lease seems redundant as the original lease has already been reviewed and approved. HCAM also recommends the application fee be based on the annual value of the leased facility and not the total value of a multi-year lease.

Encourage Nursing Facility Replacement and Renovations

Current CON regulations require a full substantive review and approval for the total replacement of an existing facility and major improvements above the capital expenditure threshold—currently set at \$3.1 million. Historically, total facility replacements and major renovations have been approved. Therefore, it doesn't seem necessary to go through the full process. It not only saves the facility costs, it would reduce the workload for the CON staff

HCAM recommends a streamlined non-substantive review process for total replacements and renovation regardless of the amount of capital expenditure or location within the planning area. This change would only apply for a replacement that does not include an increase in beds.

Combining of Nursing Facilities

Replacement can also occur by combining two old facilities into one new structure. The current interpretation is that each facility has to be replaced; it does not allow replacing two facilities into a single site under a new single license.

HCAM recommends allowing a combined facility project to obtain a single CON to replace all of the beds into a single facility within the planning area. The replacement will result in a single nursing facility with one license. The applications would be subject to the same non-substantive review as previously recommended for a replacement facility.

Requirements for Approval to Increase Beds

The standards allow an exception to the number of beds approved for high occupancy. The threshold is inconsistent within the section see part 1 (vi) (iii) (B). The first percentage is 94 percent and the second percentage is 92 percent, it seems like they should be consistent. HCAM recommends the threshold be set at 92 percent.

Addendum for Special Population Groups

HCAM recommends the criteria for each group contained in the addendum be reviewed. Are the criteria too stringent or too lenient? Why have so few of these beds actually been made available to deliver care? Do they address the intended care needs, i.e. behavioral health beds provide mental health and physical health services?

MDHHS Recommendations for CON Standards Scheduled for 2016 Review

Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing (SNN) Services			
Department Recommendation: NICU and SNN Services should continue to be regulated through CON and the recommended changes can be accomplished through the Department drafting language for the Commission to review.			
Identified Issues	Issues Recommended for Review	Recommended Course of Action to Review Issues	Other/Comments
Eliminate the language that limits the expansion of beds to no more than 5	Yes.	Department to draft language for the Commission's review.	
Develop a definition of a well newborn nursery that identifies that well newborn nurseries are not part of CON regulation.	Yes.	Department to draft language for the Commission's review.	This issue was identified by MDHHS staff as a way to clarify further what is and what is not part of CON regulation. This is a technical edit that does not make any programmatic changes in CON regulation.
Make technical edits to the definition of Special Care Nursery that will add clarity to what types of services are provided in Special Care Nurseries.	Yes.	Department to draft language for the Commission's review.	This issue was identified by MDHHS staff as a way to clarify further what is and what is not part of CON regulation. This is a technical edit that does not make any programmatic changes in CON regulation.
Other technical changes as necessary.	Yes.	Department to draft language for the Commission's review.	
Inhibit hospitals marketing to the public higher levels of NICU services than what they are actually licensed and staffed to provide	No.		This is a compliance issue and cannot be addressed in the standards.

MDHHS Staff Analysis of the Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing (SNN) 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 NICU and SNN Services Standards are scheduled for review in calendar year 2016.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 9 - 23, 2015. Testimony was received from five (5) organizations and is summarized as follows:

- 1.) *Barbara Bressick, Henry Ford Health System (HFHS)*
 - Supports the continued regulation of NICU services/beds.
 - Recommends reviewing/revising the current NICU standards within the requirements to expand a service. Currently, the maximum allowed to expand by is up to 5 beds and does not allow for flexibility within the formula even if there is a greater demand as demonstrated by the average daily census.

- 2.) *Steven Szelag on behalf of T. Anthony Denton, University of Michigan Health System (UMHS)*
 - Supports the continued regulation of NICU services/beds.
 - To validate this position, results from a study published in the *Journal of Perinatology* and the 2013 Michigan CON Annual Survey are being cited.
 - The study found that states with at least one large metropolitan area, those states with CON legislation, had significantly less level IIIB NICU's and lower infant mortality rates compared with states without CON legislation (0.54 fewer deaths/1,000 births, 95% CI 0.02 to 1.06).
 - The CON survey indicates Michigan's statewide NICU occupancy rate is 72%. This occupancy rate demonstrates that there is adequate NICU capacity in the state. (Department Note: *The 2014 survey statewide average occupancy rate is 69 percent.*)

- 3.) *Dennis McCafferty, Economic Alliance for Michigan (EAM)*
 - Supports the continued regulation of NICU services/beds.
 - Recommends reviewing the concern that some hospitals are marketing to the public that they are able to provide higher levels of NICU services than what they are actually licensed and staffed to provide.

- 4.) *Sean Gehle, Ascension Michigan*
 - Supports continued regulation of NICU services/beds and recommends no changes at this time.

- 5.) *Patrick O' Donovan, Beaumont Health*
 - Recommends continued regulation and recommends no changes at this time.

BACKGROUND

The NICU and SNN Services standards were reviewed with a workgroup in 2013-2014. During this workgroup, Special Newborn Nursing (SNN), also called Special Care Nurseries, criteria were added to the NICU beds/services standard. During 2015 providers have been applying for a CON to initiate Special Care Nurseries. The current effective date of the NICU and SNN Services standards is December 22, 2014.

2014 Annual Survey Data

Annual survey data for 2014 is the latest available and can be found here:

http://www.michigan.gov/documents/mdch/Report_030_506175_7.pdf

MDHHS Recommendations for CON Standards Scheduled for 2016 Review

Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Standards			
Department Recommendation: Deregulation of lithotripsy should be considered by a Standards Advisory Committee. If it is determined that regulation is still necessary, then the remaining issues should be addressed by the Standards Advisory Committee (SAC).			
Identified Issues	Issue Recommended for Review?	Recommended Course of Action to Review Issues:	Other/Comments:
Consider the necessity of continued regulation.	Yes.	Form a SAC	
Review Standards to determine appropriate criteria to allow for conversion from mobile to fixed equipment once a certain volume threshold has been met	Yes.	Form a SAC	
Review the volume requirement for expansion	Yes.	Form a SAC	Issue identified by the CON Evaluation Section
Review Standards to determine if separate requirements are necessary for freestanding sites, as several criteria are only reasonably feasible for hospitals.	Yes.	Form a SAC	Issue identified by the CON Evaluation Section

MDHHS 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 2016.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 9 - 23, 2015. Testimony was received from eight (8) organizations and is summarized as follows:

- 1.) *Steven Szelag on behalf of T. Anthony Denton, University of Michigan Health System*
 - Recommends convening an informal workgroup to evaluate the necessity for continued CON regulation of this service.
- 2.) *Alan Burgenthal, Greater Michigan Lithotripsy, LLC*
 - Strongly supports the continued regulation of UESWL services through the current CON standards.
- 3.) *Jorgen Madsen, United Medical Systems*
 - Strongly supports the continued regulation of UESWL services.
 - States in Michigan that capacity and demand are in very good balance, resulting in great access with stable pricing.
 - States the system in place under the current standards allows for broad geographic access by encouraging large volume sites to maintain mobile service which then supports mobile routes that also provide service to low volume rural sites.
 - Further, 18% of lithotripsy host sites in the State of Michigan are located in rural or micropolitan statistical area counties. They only account for 9% of total lithotripsy procedures, but they are still able to provide this service to their patients utilizing the same equipment at the same price with highly experienced technologists operating the equipment.
- 4.) *Dennis McCafferty, Economic Alliance for Michigan (EAM)*
 - Supports regulation of this service.
 - States that the CON website's most current survey report is from 2012, and are not able to make comments regarding utilization and access.
 - States that they hope that more current survey information is made available prior to the January Planning meeting. (Department note: *This data was published in November 2015.*)
- 5.) *Patrick O' Donovan, Beaumont Health*
 - Supports continued regulation and recommends no changes at this time.
- 6.) *Sean Gehle, Ascension Michigan*
 - Supports continued regulation and recommends no changes at this time.
- 7.) *Marc Chircop, Spectrum Health*
 - Supports continued regulation and recommends no changes at this time.
- 8.) *John A. Shaski, Sparrow Health System*

- Supports continued regulation through CON.
- States that the availability of mobile lithotripsy services has limited Sparrow's campus to time on a mobile network only twice a month. The narrow window of available service time is not sufficient to treat patients in a timely fashion.
- States the methodology requires 100% MIDB data commitment for five years from the time a CON approved service becomes operational. A hospital currently providing Lithotripsy services cannot commit any MIDB data to a new application. The combined effect of these provisions is that a hospital's data is committed forever once it begins a Lithotripsy service (fixed or mobile), regardless of changes in patient need.
- Recommends bringing Lithotripsy services in line with other CON Review Standards like Magnetic Resonance Imaging (MRI) allowing for conversion from mobile to fixed equipment once a certain volume threshold has been met, or Computed Tomography (CT) allowing for development of new mobile networks based on existing patient volume.
- Recommends formation of Standard Advisory Committee (SAC) or workgroup to address both access and cost concerns.

2014 Annual Survey Data

The 2014 Annual Survey data is the latest available and can be viewed at:

Host Site Report:

http://www.michigan.gov/documents/mdch/Report_090_506618_7.pdf

Mobile Providers Report:

http://www.michigan.gov/documents/mdch/Report_092_506619_7.pdf

Central Service Coordinators and Host Sites by Mobile Route Report

http://www.michigan.gov/documents/mdch/Report_094_506621_7.pdf

CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2015												2016											
	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 (AA)										PC	.	.	•R A											
Bone Marrow Transplantation (BMT) Services**	•R A		DA	.	.	•S	•S	•S	•S	•S	■	■	■	■	■	■	■	•R	•P	.	•▲ F			
Computed Tomography (CT) Scanner										PC	.	.	•R A											
Magnetic Resonance Imaging (MRI) Services**	•R A	•R	.	•P	•▲ F									
Neonatal Intensive Care Services/Beds and Special Newborn Nursing Services										PC	.	.	•R A											
Nursing Home and Hospital Long-Term-Care Unit (NH-HLTCU) Beds										PC	.	•A	•R A	.	•A									
Psychiatric Beds and Services**	•R A	•R	.	.	•R	•P	.	•▲ F						
Urinary Extracorporeal Shock Wave Lithotripsy Services										PC	.	.	•R A											
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			•M			•M
FY2015 CON Annual Activity Report															R									

- 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
 - PC - Public Comment Period for initial comments on review standards for review in the upcoming year
 - R - Receipt of report
 - S - Solicit nominations for standard advisory committee or standing committee membership

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

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	June 2, 2014	2016
Bone Marrow Transplantation Services	September 29, 2014	2018
Cardiac Catheterization Services	September 14, 2015	2017
Computed Tomography (CT) Scanner Services	December 22, 2014	2016
Heart/Lung and Liver Transplantation Services	September 28, 2012	2018
Hospital Beds	March 20, 2015	2017
Magnetic Resonance Imaging (MRI) Services	December 22, 2014	2018
Megavoltage Radiation Therapy (MRT) Services/Units	September 14, 2015	2017
Neonatal Intensive Care Services/Beds (NICU)	December 22, 2014	2016
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	March 20, 2015	2016
Open Heart Surgery Services	June 2, 2014	2017
Positron Emission Tomography (PET) Scanner Services	September 14, 2015	2017
Psychiatric Beds and Services	March 22, 2013	2018
Surgical Services	December 22, 2014	2017
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	December 22, 2014	2016

*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 Comment Period 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.