From: DoNotReply@michigan.gov
To: MDHHS-ConWebTeam
Subject: 2016 CON Standards Public Comment (ContentID - 306550)
Date: Friday, October 23, 2015 2:02:00 PM

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1. Name: Sean Gehle
2. Organization: Ascension Michigan
3. Phone: 517-482-1422
4. Email: sean.gehle@stjohn.org
5. Standards: AA

6._Testimony: Ascension Michigan supports continued regulation of Air Ambulance Services. We do not suggest any modificaiton to the Air Ambulance Services standard at this time.

7. Testimony:

From: DoNotReply@michigan.gov
To: MDHHS-ConWebTeam
Subject: 2016 CON Standards Public Comment (ContentID - 306550)
Date: Friday, October 23, 2015 2:09:21 PM

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1. Name: Sean Gehle
2. Organization: Ascension Michigan
3. Phone: 517-482-1422
4. Email: sean.gehle@stjohn.org
5. Standards: UESWL
6._Testimony: Ascension Michigan supports continued regulation of Lithotripsy services. We do not suggest any modification to UESWL standards at this time.
7. Testimony:

From:	DoNotReply@michigan.gov
To:	MDHHS-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Friday, October 23, 2015 2:06:58 PM

1. Name: Sean Gehle
2. Organization: Ascension Michigan
3. Phone: 517-482-1422
4. Email: sean.gehle@stjohn.org
5. Standards: NH-HLTCU
6._Testimony: Ascension Michigan supports continued regulation of Nursing Home - Hospital Long Term Care Beds. We do not suggest any modifications to Nursing Home - Hospital Long Term care bed standards at this time.
7. Testimony:

From:	DoNotReply@michigan.gov
To:	MDHHS-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Friday, October 23, 2015 2:05:17 PM

1. Name: Sean Gehle
2. Organization: Ascension Michigan
3. Phone: 517-482-1422
4. Email: sean.gehle@stjohn.org
5. Standards: NICU
6._Testimony: Ascension Michigan supports continued regulation of NICU and Special Newborn Nursing Services/Beds. We do not suggest any modifications to the NICU and Special Newborn Nursing Services/Beds standards at this time.
7. Testimony:

From: DoNotReply@michigan.gov
To: MDHHS-ConWebTeam
Subject: 2016 CON Standards Public Comment (ContentID - 306550)
Date: Thursday, October 22, 2015 4:21:11 PM

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1. Name: Patrick O'Donovan
2. Organization: Beaumont Health
3. Phone: 248-551-6406
4. Email: Patrick.O'Donovan@Beaumont.org
5. Standards: AA
6._Testimony: Beaumont Health has reviewed the current C.O.N. Review Standards for Air Ambulance Services and recommends continued regulation under C.O.N. At this time Beaumont Health has no recommended changes to these Standards.
7. Testimony:

From:	DoNotReply@michigan.gov
To:	MDHHS-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Thursday, October 22, 2015 4:22:56 PM

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1. Name: Patrick O'Donovan
2. Organization: Beaumont Health
3. Phone: 248-551-6406
4. Email: Patrick.O'Donovan@Beaumont.org
5. Standards: CT
6._Testimony: Beaumont Health has reviewed the current C.O.N. Review Standards for CT Scanner Services and recommends continued regulation under C.O.N. At this time Beaumont Health has no recommended changes to these Standards.
7. Testimony:

From: DoNotReply@michigan.gov
To: MDHHS-ConWebTeam
Subject: 2016 CON Standards Public Comment (ContentID - 306550)
Date: Thursday, October 22, 2015 4:28:03 PM

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1. Name: Patrick O'Donovan
2. Organization: Beaumont Health
3. Phone: 248-551-6406
4. Email: Patrick.O'Donovan@Beaumont.org
5. Standards: UESWL

6._Testimony: Beaumont Health has reviewed the current C.O.N. Review Standards for UESWL Services/Units and recommends continued regulation under C.O.N. At this time Beaumont Health has no recommended changes to these Standards.

7. Testimony:

From: DoNotReply@michigan.gov
To: MDHHS-ConWebTeam
Subject: 2016 CON Standards Public Comment (ContentID - 306550)
Date: Thursday, October 22, 2015 4:26:33 PM

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1. Name: Patrick O'Donovan
2. Organization: Beaumont Health
3. Phone: 248-551-6406
4. Email: Patrick.O'Donovan@Beaumont.org
5. Standards: NH-HLTCU
6._Testimony: Beaumont Health has reviewed the current C.O.N. Review Standards for NH-HLTCU Beds and recommends continued regulation under C.O.N. At this time Beaumont Health has no recommended changes to these Standards.
7. Testimony:

From:	DoNotReply@michigan.gov
To:	MDHHS-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Thursday, October 22, 2015 4:24:51 PM

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1. Name: Patrick O'Donovan
2. Organization: Beaumont Health
3. Phone: 248-551-6406
4. Email: Patrick.O'Donovan@Beaumont.org
5. Standards: NICU

6._Testimony: Beaumont Health has reviewed the current C.O.N. Review Standards for NICU and Special Newborn Nursing Services/Beds and recommends continued regulation under C.O.N. At this time Beaumont Health has no recommended changes to these Standards.

7. Testimony:

From: DoNotReply@michigan.gov
To: MDHHS-ConWebTeam
Subject: 2016 CON Standards Public Comment (ContentID - 306550)
Date: Thursday, October 22, 2015 10:48:37 AM

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1. Name: Dennis McCafferty
2. Organization: Economic Alliance for Michigan
3. Phone: 248-596-1006
4. Email: DennisMccafferty@EAMOnline.org
5. Standards: AA
6._Testimony: The last time this standard was reviewed in 2014, the consensus of the "work group" was that the patient safety and quality provision for Air Ambulance Services only existed in the CON Standards. Before this CON Standard could be Deregulated, these patient safety and quality provisions needed to be replicated in the other State's regulations of emergency transportation services. We were told that this would take up to two years to accomplish. We are not aware if this has yet been accomplished. If not, our members would be reluctant to support recommendations to Deregulate Air Ambulance Services.

On a related note, the CON survey reports for Air Ambulance Services are "Not Yet Reported" for 2013 and no survey reports have been posted for 2014. Therefore it is difficult to submit comments when we are not able to know what the CON regulated Air Ambulance Services are doing.

7. Testimony:

From:	DoNotReply@michigan.gov
To:	MDHHS-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Thursday, October 22, 2015 10:56:35 AM

1. Name: Dennis McCafferty
2. Organization: Economic Alliance for Michigan
3. Phone: 248-596-1006
4. Email: Dennismccafferty@
5. Standards: CT
6._Testimony: While our members support the continued regulation of CT services,it is difficult for us to comment on what issue may exist for this Standard. The four CON Survey reports for CT Services (100, 102, 104, 107) have yet to be made available for 2013 and the 2014 Survey Reports are not available for any of the CON covered services.

We look forward to the comments made by others and hope that more current Survey information could be made public prior to the January Planning meeting.
7. Testimony:

From:	DoNotReply@michigan.gov
To:	MDHHS-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Thursday, October 22, 2015 11:46:14 AM

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1. Name: Dennis McCafferty
2. Organization: Economic Alliance for Michigan
3. Phone: 248-596-1006
4. Email: Dennismccafferty@EAMOnline.org
5. Standards: UESWL
6._Testimony: Our members have continued to support the continued regulation of this service. However, because the CON website's most current survey report is from 2012, we are unable to make comments regarding utilization and access. We look forward to reviewing the comments from other and hope that more current survey information is made available prior to the January Planning meeting.
7. Testimony:

From:	DoNotReply@michigan.gov
To:	MDHHS-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Thursday, October 22, 2015 11:41:46 AM

1. Name: Dennis McCafferty
2. Organization: Economic Alliance for Michigan
3. Phone: 248-596-1006
4. Email: Dennismccafferty@EAMOnline.org
5. Standards: NICU
6._Testimony: Our members would support continued regulation of this service.
Based upon the most recent information available on the CON website, Survey report from 2013, we note that several NICU units have very high occupancy rates (90% or more). Not sure what this means related to access.

The last time this service was reviewed by a work group, there was a concern that some hospitals were marketing to the public that they were able to provide higher levels of NICU services than what they were actually licensed and staffed to provide. We would like this issue reviewed again by a work group.
7. Testimony:

From: DoNotReply@michigan.gov
To: MDHHS-ConWebTeam
Subject: 2016 CON Standards Public Comment (ContentID - 306550)
Date: Friday, October 23, 2015 2:17:48 PM

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1. Name: John A. Shaski
2. Organization: Sparrow Health System
3. Phone: 517.364.3534
4. Email: john.shaski@sparrow.org
5. Standards: UESWL
6._Testimony: Dr. Marc Keshishian
Chair, Certificate of Need Commission
Department of Health and Human Services
Grand Tower Building, 235 S. Grand Avenue
Lansing, MI 48933

Re: Urinary Extracorporeal Shock Wave (UESWL) Lithotripsy Services

Dear Dr. Keshishian:

Sparrow Health System appreciates the opportunity to provide testimony to the Certificate of Need Commission regarding Urinary Extracorporeal Shock Wave (UESWL) Lithotripsy Services.

Sparrow Health has been a long time provider of high quality comprehensive health care services throughout the Mid-Michigan region. As such, we added mobile Lithotripsy services to meet patient care needs in 1989. Over the past 26 years our program has grown with advancements in technology and patient demand for services.

Our patients' needs are our number one priority. Yet, the availability of mobile lithotripsy services has limited our campus to time on a mobile network only twice a month. The narrow window of available service time is not sufficient to treat our patients in a timely fashion – which is particularly problematic when taking into account the emergent nature of these diagnoses and level of pain management required.

To further complicate matters, the methodology outlined in the Certificate of Need Review Standards requires a 100% MIDB data commitment for five years from the time a CON approved service becomes operational. Further, a hospital currently providing Lithotripsy services cannot commit any MIDB data to a new application. The combined effect if 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.

The unintended consequence of the current Review Standards is that the patients bear the cost of waiting in significant pain; or being forced to travel to another facility that may or may not have access to the much needed services.

Several other CON Covered Clinical services have encountered similar circumstances and have developed language that assists health care providers in creating a regulatory pathway to meet growing patient demand through reasonable means. Specifically Magnetic Resonance Imaging (MRI) allows for conversion from mobile to fixed equipment once a certain volume threshold has been met. Or Computed Tomography (CT) allows for development of new mobile networks based on existing patient volume. Bringing Lithotripsy in line with other sets of CON Review Standards will create an environment that is more flexible for patients and more efficient for providers.

For these reasons, Sparrow Health respectfully asks the Commission to form either a Standards Advisory Committee (SAC) or workgroup to address both access and cost concerns. We look forward to working with the Commission on this issue.

Sincerely,

John A. Shaski
Government Relations Officer
7. Testimony:

From:	DoNotReply@michigan.gov
To:	MDHHS-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Wednesday, October 21, 2015 8:57:35 AM
Attachments:	GML2016UESWLCONReviewComments.pdf

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1. Name: Alan Buergenthal
2. Organization: Greater Michigan Lithotripsy, LLC
3. Phone: 614-298-8150
4. Email: abuergenthal@aksm.com
5. Standards: UESWL
6._Testimony:

Content-Length: 802092

Greater Michigan Lithotripsy, LLC

October 21, 2015

Mark D. Keshishian, M.D.
Chairperson
Certificate of Need Commission
c/o Michigan Department of Health & Human Services
201 Townsend Street
Lansing, Michigan 48913

Re: CON Review Standards for Urinary Extracorporeal Shock Wave Lithotripsy ("UESWL") Services/Units

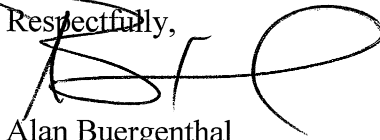
Dear Chairperson Keshishian:

Greater Michigan Lithotripsy, LLC ("GML") appreciates the opportunity to provide written testimony to the Commission on changes, if any, that are needed with regard to CON Review Standards for UESWL Services/Units.

GML does not believe that any changes to the current UESWL CON standards are necessary at this time. GML strongly supports the continued CON regulation of UESWL as an effective means of controlling costs and maintaining the quality of UESWL Services in Michigan.

Thank you for your consideration of our comments.

Respectfully,



Alan Buergenthal
CEO of American Kidney Stone Management, Ltd.,
Manager of Greater Michigan Lithotripsy, LLC

Managed By:
American Kidney Stone Management, Ltd.
100 West 3rd Avenue
Suite350
Columbus, Ohio 43201

From:	DoNotReply@michigan.gov
To:	MDHHS-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Friday, October 23, 2015 8:48:32 AM
Attachments:	HCAM_2015_CON_Comments_Oct_23_2015.pdf

1. Name: Pat Anderson
2. Organization: Health Care Association of Michigan
3. Phone: 517-627-1561
4. Email: patanderson@hcam.org
5. Standards: NH-HLTCU

6._Testimony: Thank you for the opportunity to comment on the NH-HLTCU standards. If you have questions on our comments contact me.

Content-Length: 322663

hcam
PROMOTING EXCELLENCE IN SENIOR CARE

7413 Westshire Drive
Lansing, Michigan 48917

Phone: (517) 627-1561
Fax: (517) 627-3016
Web: www.hcam.org

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 following minor recommendations to streamline the process and add greater flexibility for providers and the state, while maintaining the value and focus of CON.

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.

Most Michigan nursing facilities were built decades ago. To meet today's resident's needs and expectations, nursing facilities should be replaced or renovated. 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.

> Non-substantive review is not onerous and is well known to current providers. Granting (1) non-substantive review and (2) placement anywhere in the planning area will encourage these projects without repealing all of the ongoing CON requirements applied to all other nursing facilities.
>
> Applicants would still need to meet quality and financial requirements, including:
> - An applicant has a viable financing and fiscal plan;
> - A regulatory history in Michigan and other states that is that is acceptable under the current standards;
> - A commitment to the annual CON reporting requirements imposed on all nursing facilities;
> - A commitment that current residents are offered the chance to move to a replacement facility.

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 costs, it would reduce the workload for the CON staff.

October 14, 2015

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.

It seems to be more efficient to create one structure and not require two separate buildings that are next to each other. This limitation suppresses the replacement of older buildings with modern buildings within the population of existing beds.

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.

This allows the updating and downsizing of large older facilities. It helps providers meet the expectations of aging "baby boomers."

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.

This would provide holders of approved CON's for new construction projects flexibility in identifying the best location. Bed need is determined by county boundaries, but does not specify any particular area within a county. There is no harm or downside in allowing new projects the flexibility of changing location within replacement zone of the original CON application site.

Requirements for Approval to Renew Existing Leases
It is unclear why a renewal of a lease arrangement is included in CON review as it is for acquisition of an existing facility.

HCAM recommends requiring only a waiver be filed when a lease renewal at the existing site does not involve changes to access or quality. Further, 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.

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.

<u>Other Issues To Be Address</u>

Requirements for Approval to Increase Beds
The standards allow an exception to the number of beds approved for high occupancy. The threshold is very high considering the current environment and 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 at 92 percent. 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 cover the desired care to needs to be addressed, i.e. behavioral health beds which cover mental health conditions?

Bed Need Should Accurately Reflect Current Population Needs
HCAM recommends reviewing the formula and data sources used to determine bed supply and need.

From:	DoNotReply@michigan.gov
To:	MDHHS-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Friday, October 23, 2015 2:12:19 PM
Attachments:	CON_2016_Public_Comment.HFHS_NICU.pdf

1. Name: Barbara Bressack
2. Organization: Henry Ford Health System
3. Phone: 3138746665
4. Email: bbressa1@hfhs.org
5. Standards: NICU
6._Testimony:

Content-Length: 530106

Henry Ford Health System
One Ford Place – Suite 4A
Detroit, MI 48202
(313) 874-6665

October 23, 2015

Marc D. Keshishian, M.D.
CON Commission Chairperson
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Keshishian:

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need review standards for Neonatal Intensive Care Services/Beds (NICU). Henry Ford Health System supports the continued regulation of NICU services and offers the following proposed areas of focus: Review/revise the current NICU standards within the requirements to expand a service. Currently there is a maximum of expanding by up to 5 beds and does not allow for flexibility within the formula even if there is greater demand as demonstrated by the average daily census.

Review of the bed need methodology in light of the SCN changes and potential increased demand to the existing NICU's. Due to the stricter rules about what can be done in level 2 nurseries versus NICU, we are seeking greater flexibility within these standards for the potential increased demand.

We look forward to working with the Commission and the Department to discuss this issue.

Respectfully,

Barbara Bressack

Barbara Bressack
Henry Ford Health System
Director, Planning & CON Strategy

From:	DoNotReply@michigan.gov
To:	MDHHS-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Friday, October 23, 2015 1:51:33 PM
Attachments:	CON_2016_Public_Comment.HFHS_AA.pdf

1. Name: Barbara Bressack
2. Organization: Henry Ford Health System
3. Phone: 3138746665
4. Email: bbressa1@hfhs.org
5. Standards: AA
6._Testimony:

Content-Length: 441448

Henry Ford Health System
One Ford Place – Suite 4A
Detroit, MI 48202
(313) 874-6665

October 23, 2015

Marc D. Keshishian, M.D.
CON Commission Chairperson
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Keshishian:

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need review standards for Air Ambulance services:

Henry Ford Health System strongly supports the Commission's decision 3 years ago to continue regulating air ambulance services until the administrative rules for EMS are updated to ensure the administrative rules contain all of the same requirements as the current CON standards. We are not aware that those rules have been updated yet and so would request continued regulation, without revision, at this time.

Respectfully,

Barbara Bressack

Barbara Bressack
Henry Ford Health System
Director, Planning & CON Strategy
One Ford Place, 4A
Detroit, MI 48202

From:	DoNotReply@michigan.gov
To:	MDHHS-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Wednesday, October 21, 2015 4:18:24 PM
Attachments:	MAASCON2015.pdf

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1. Name: Kelly Ann Hekler
2. Organization: Michigan Association of Ambulance Services
3. Phone: 517-485-3376
4. Email: kelly@miambulance.org
5. Standards: AA
6._Testimony:

Content-Length: 351404

MAAS
MICHIGAN ASSOCIATION OF AMBULANCE SERVICES

517.485.3376 2123 University Park Dr. • Suite 100 • Okemos, MI 48864 www.miambulance.org

October 19, 2015

Marc Keshishian, M.D. - CON Commission Chairperson
Certificate of Need Policy
Capitol View Building
201 Townsend Street
Lansing, MI 48913

RE: Air Ambulance Services - Certificate of Need Standards Review

Dear Commissioner Keshishian:
The Michigan Association of Ambulance Services (MAAS) supports the continued application of Certification of Need (CON) for air ambulance services in Michigan.

MAAS understands that the CON no longer has the ability to regulate need as it pertains to Air Ambulance due to a recent Federal ruling. MAAS also understands that the Emergency Medical Services (EMS) Section recently initiated the rule making process to update their program to address quality in Air Ambulance. Until this process is complete and new rules are in effect within the EMS regulations; the CON Standards for Air Ambulance should remain effect.

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 states. With today's limited healthcare dollars, it is important that we avoid using aircraft for unnecessary and expensive modes of transport. Overutilization increases the cost of healthcare for everyone and has the potential of necessitating increased subsidies from local governments as well.

The air medical CON assures patient safety and without it or changes within the EMS regulations may increase the risk of accidents and the potential of overutilization. One has only to look to neighboring states and the number of helicopters to understand what could occur in Michigan.

We would welcome the opportunity to discuss further and thank you for the allowing MAAS to express its opinion.

Respectfully submitted,

From:	DoNotReply@michigan.gov
To:	MDHHS-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Wednesday, October 21, 2015 4:18:24 PM
Attachments:	MAASCON2015.pdf

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1. Name: Kelly Ann Hekler
2. Organization: Michigan Association of Ambulance Services
3. Phone: 517-485-3376
4. Email: kelly@miambulance.org
5. Standards: AA
6._Testimony:

Content-Length: 351404

MAAS
MICHIGAN ASSOCIATION OF AMBULANCE SERVICES

517.485.3376 2123 University Park Dr. • Suite 100 • Okemos, MI 48864 www.miambulance.org

October 19, 2015

Marc Keshishian, M.D. - CON Commission Chairperson
Certificate of Need Policy
Capitol View Building
201 Townsend Street
Lansing, MI 48913

RE: Air Ambulance Services - Certificate of Need Standards Review

Dear Commissioner Keshishian:
The Michigan Association of Ambulance Services (MAAS) supports the continued application of Certification of Need (CON) for air ambulance services in Michigan.

MAAS understands that the CON no longer has the ability to regulate need as it pertains to Air Ambulance due to a recent Federal ruling. MAAS also understands that the Emergency Medical Services (EMS) Section recently initiated the rule making process to update their program to address quality in Air Ambulance. Until this process is complete and new rules are in effect within the EMS regulations; the CON Standards for Air Ambulance should remain effect.

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 states. With today's limited healthcare dollars, it is important that we avoid using aircraft for unnecessary and expensive modes of transport. Overutilization increases the cost of healthcare for everyone and has the potential of necessitating increased subsidies from local governments as well.

The air medical CON assures patient safety and without it or changes within the EMS regulations may increase the risk of accidents and the potential of overutilization. One has only to look to neighboring states and the number of helicopters to understand what could occur in Michigan.

We would welcome the opportunity to discuss further and thank you for the allowing MAAS to express its opinion.

Respectfully submitted,

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

October 21, 2015

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

Re: CON Standards for Computed Tomography (CT) Services

Dear Chairman Keshishian,

It is my understanding that the CON Commission will be reviewing the CON Standards for CT services this coming year, and that part of that review will be considering whether or not CT services should continue to be covered under Michigan's CON program. On behalf of the Michigan Dental Association, I am writing to respectfully request the Commission to consider the deregulation of dental CT services specifically.

The Michigan Dental Association appreciates the improvements that have been made to the CT standards as they relate to dental CT services, as well as the efforts made by the Department to publish instructions geared specifically toward dentists to try to help make the process more manageable. However, the fact remains that 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 hurtles put in place by the CON process in Michigan. Michigan remains one of only two states still regulating this technology under CON. It is also the least expensive technology regulated by CON in this state. The average CBCT (i.e. dental CT) costs less than $100,000 and is comparable to a panoramic x-ray machine, which any dentist can purchase without CON. CBCT merely allows the dentist to view the images taken in the third dimension, allowing them to provide better treatment to their patients.

Thank you for this opportunity to provide input on these standards. I hope you will take this request into consideration as you determine what changes should be made to the CT standards in 2016. Please don't hesitate to contact me directly with any question at (517) 346-9405.

Respectfully,

Bill Sullivan

Bill Sullivan, J.D.
Director of Government and Insurance Affairs

CC: Sen. Mike Shirkey, Chair, Senate Health Policy Committee
Rep. Mike Callton, Chair, House Health Policy Committee

From:	DoNotReply@michigan.gov
To:	MDHHS-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Friday, October 23, 2015 3:46:17 PM
Attachments:	Spectrum_Litho_Comments_10-21-15.pdf

1. Name: Marc Chircop
2. Organization: Spectrum Health
3. Phone: 6163911774
4. Email: marc.chircop@spectrumhealth.org
5. Standards: UESWL
6._Testimony: See letter.

Content-Length: 35833

Spectrum Health System

100 Michigan Street NE / MC 005
Grand Rapids, MI 49503
616.391.1774
spectrum-health.org

October 21, 2015

Mark D. Keshishian, M.D.
Chairperson
Certificate of Need Commission
c/o Michigan Department of Health & Human Services
201 Townsend Street
Lansing, Michigan 48913

Re: 2016 CON Review - Urinary Extracorporeal Shock Wave Lithotripsy ("UESWL") Services/Units

Dear Chairperson Keshishian:

Spectrum Health thanks the Commission for the opportunity to provide written testimony on the need for continued CON regulation of UESWL Services/Units.

Spectrum Health believes that maintaining CON regulation of UESWL Services/Units will continue to serve the citizens of Michigan well. We do not believe there is any need to make changes to the UESWL Services/Units standards that are currently in effect.

We appreciate the Commission's consideration of our comments.

Respectfully submitted,

Marc Chircop
Senior Vice President, Regional Relationships

From:	DoNotReply@michigan.gov
To:	MDHHS-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Friday, October 23, 2015 2:12:37 PM
Attachments:	Spectrum_NHBed_Comments_10-21-15.pdf

1. Name: Chad Tuttle
2. Organization: Spectrum Health
3. Phone: 6164862404
4. Email: Chad.Tuttle@spectrumhealth.org
5. Standards: NH-HLTCU
6._Testimony: See letter.

Content-Length: 47505

SPECTRUM HEALTH

Spectrum Health Continuing Care
Executive Administration | MC033
750 Fuller Avenue NE
Grand Rapids, MI 49503
www.spectrumhealth.org/continuingcare

October 21, 2015

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

Re: CON Standards for Nursing Home/HLTCU Beds

Dear Chairman Keshishian,

This letter is submitted as formal testimony regarding the CON Review Standards for Nursing Home and HLTCU Beds which went into effect March 20, 2015. Spectrum Health appreciates the opportunity to comment on these Standards.

At the CON Commission meeting held September 24, 2015 the Department presented the updated bed need according to the methodology in the Standards. This updated bed need showed a decrease in beds in every single planning area across the State. Given that studies and industry projections would suggest an increased need for long-term care beds as the baby boomers continue to age, many have called into question the methodology and/or the data being used to run the methodology.

We appreciate the Commission's decision to delay making the updated bed need effective while the Department seeks answers. We would encourage the Commission to keep this concern in the forefront when deciding what level of review of the standards is warranted in 2016. Depending upon the answers received, the Commission may want to have a Standards Advisory Committee or Workgroup review the methodology and data sources and recommend changes to ensure Certificate of Need does not hinder the ability of our nursing homes to meet the demands of our aging population.

Spectrum Health appreciates the opportunity to comment on the CON Review Standards for Nursing Home and HLTCU Beds and will be pleased to participate in this process as appropriate.

Sincerely,

Chad Tuttle
President, Spectrum Health Continuing Care

From: DoNotReply@michigan.gov
To: MDHHS-ConWebTeam
Subject: 2016 CON Standards Public Comment (ContentID - 306550)
Date: Tuesday, October 20, 2015 3:06:40 PM
Attachments: UMHS_Air_Amb_Public_Comment_23Oct2015.pdf

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1. Name: Steven Szelag
2. Organization: University of Michigan Health System
3. Phone: (734) 647-1163
4. Email: sszelag@umich.edu
5. Standards: AA
6._Testimony:

Content-Length: 768326

HOSPITALS & HEALTH CENTERS
UNIVERSITY OF MICHIGAN HEALTH SYSTEM

T. Anthony Denton
Acting Chief Executive Officer
and Chief Operating Officer

University of Michigan Hospitals
And Health Centers
300 N. Ingalls St, SPC 5474
Ann Arbor MI 48109-0400

T: (734) 764-1505
F: (734) 763-5311

tadpole@med.umich.edu
uofmhealth.org

October 23, 2015

Marc Keshishian, M.D. - CON Commission Chairperson
Certificate of Need Policy
Capitol View Building
201 Townsend Street
Lansing, MI 48913

RE: Air Ambulance Services - Certificate of Need Standards Review

Dear Commissioner Keshishian:

This letter is written as formal testimony pertaining to the Certificate of Need (CON) Review Standards for Air Ambulance Services. The University of Michigan Health System (UMHS) supports the continued regulation of this covered service. UMHS understands that CON no longer has the ability to regulate need as it pertains to Air Ambulance due to a recent Federal ruling. UMHS also understands that the Emergency Medical Services (EMS) Section recently initiated the rule-making process to update their program to address quality in Air Ambulance. Until this process is complete and new rules are in effect within the EMS regulations, the CON Standards for Air Ambulance should remain in effect.

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,

T. Anthony Denton
Acting Chief Executive Officer and Chief Operating Officer

From:	DoNotReply@michigan.gov
To:	MDHHS-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Tuesday, October 20, 2015 3:05:32 PM
Attachments:	UMHS_CT_Public_Comment_23Oct2015.pdf

1. Name: Steven Szelag
2. Organization: University of Michigan Health System
3. Phone: (734) 647-1163
4. Email: sszelag@umich.edu

5. Standards: CT
6._Testimony:

Content-Length: 730559

HOSPITALS & HEALTH CENTERS
UNIVERSITY OF MICHIGAN HEALTH SYSTEM

T. Anthony Denton
Acting Chief Executive Officer
and Chief Operating Officer

University of Michigan Hospitals and Health Centers
300 N. Ingalls St, SPC 5474
Ann Arbor MI 48109-0400

T: (734) 764-1505
F: (734) 763-5311

tadpole@med.umich.edu
uofmhealth.org

October 23, 2015

Marc Keshishian, M.D. - CON Commission Chairperson
Certificate of Need Policy
Capitol View Building
201 Townsend Street
Lansing, MI 48913

RE: Computed Tomography Services - Certificate of Need Standards Review

Dear Commissioner Keshishian:

This letter is written as formal testimony pertaining to the Certificate of Need (CON) Review Standards for Computed Tomography (CT) Services. The University of Michigan Health System (UMHS) has supported the continued regulation of this service for many years; however, it may now be the time to open these standards and determine whether or not the existing regulations are meeting the intended goals of balancing cost, quality and access. UMHS recommends convening an informal workgroup to evaluate the necessity for continued CON regulation of CT.

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,

T. Anthony Denton
Acting Chief Executive Officer and Chief Operating Officer

From:	DoNotReply@michigan.gov
To:	MDHHS-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Tuesday, October 20, 2015 3:11:30 PM
Attachments:	UMHS_Lithotripsy_Public_Comment_23Oct2015.pdf

1. Name: Steven Szelag
2. Organization: University of Michigan Health System
3. Phone: (734) 647-1163
4. Email: sszelag@umich.edu
5. Standards: UESWL
6._Testimony:

Content-Length: 745928

HOSPITALS & HEALTH CENTERS
UNIVERSITY OF MICHIGAN HEALTH SYSTEM

T. Anthony Denton
Acting Chief Executive Officer
and Chief Operating Officer

University of Michigan Hospitals
and Health Centers
300 N. Ingalls St, SPC 5474
Ann Arbor MI 48109-0400

T: (734) 764-1505
F: (734) 763-5311

tadpole@med.umich.edu
uofmhealth.org

October 23, 2015

Marc Keshishian, M.D. - CON Commission Chairperson
Certificate of Need Policy
Capitol View Building
201 Townsend Street
Lansing, MI 48913

RE: Lithotripsy Services - Certificate of Need Standards Review

Dear Commissioner Keshishian:

This letter is written as formal testimony pertaining to the Certificate of Need (CON) Review Standards for Lithotripsy Services. The University of Michigan Health System (UMHS) has supported the continued regulation of this service for many years; however, it may now be the time to open these standards and determine whether or not the existing regulations are meeting the intended goals of balancing cost, quality and access. UMHS recommends convening an informal workgroup to evaluate the necessity for continued CON regulation of this service.

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,

T. Anthony Denton
Acting Chief Executive Officer and Chief Operating Officer

From:	DoNotReply@michigan.gov
To:	MDHHS-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Tuesday, October 20, 2015 3:09:03 PM
Attachments:	UMHS_NICU_Public_Comment_23Oct2015.pdf

1. Name: Steven Szelag
2. Organization: University of Michigan Health System
3. Phone: (734) 647-1163
4. Email: sszelag@umich.edu
5. Standards: NICU
6._Testimony:

Content-Length: 1341959

M | HOSPITALS & HEALTH CENTERS
UNIVERSITY OF MICHIGAN HEALTH SYSTEM

T. Anthony Denton
Acting Chief Executive Officer
and Chief Operating Officer

University of Michigan Hospitals
and Health Centers
300 N. Ingalls St, SPC 5474
Ann Arbor MI 48109-0400

T: (734) 764-1505
F: (734) 763-5311

tadpole@med.umich.edu
uofmhealth.org

October 23, 2015

Marc Keshishian, M.D. - CON Commission Chairperson
Certificate of Need Policy
Capitol View Building
201 Townsend Street
Lansing, MI 48913

RE: Neonatal Intensive Care Unit Services - Certificate of Need Standards Review

Dear Commissioner Keshishian:

This letter is written as formal testimony pertaining to the Certificate of Need (CON) Review Standards for Neonatal Intensive Care Unit (NICU) Services. The University of Michigan Health System (UMHS) supports the continued regulation of this covered service. To help 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 fewer level IIIB NICUs. The study also found that states with at least one large metropolitan area, states with CON legislation, had significantly 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 is at 72.7%. This occupancy rate demonstrates that there is adequate NICU capacity in the state. These findings would suggest that CON is meeting its intended goals of balancing cost, quality and access as it relates to this service. It is for these reasons that UMHS believes no changes to the standards are required and that they should not be opened at this time.

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,

T. Anthony Denton
Acting Chief Executive Officer and Chief Operating Officer

Attachments: The Impact of Certificate of Need Programs on Neonatal Intensive Care Units
2013 Michigan CON Annual Survey – NICU Services

Journal of Perinatology (2012) 32, 39–44
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www.nature.com/jp

ORIGINAL ARTICLE

The impact of certificate of need programs on neonatal intensive care units

SA Lorch[1,2,3], P Maheshwari[4] and O Even-Shoshan[2,5]

[1]Department of Pediatrics, The Children's Hospital of Philadelphia and The University of Pennsylvania School of Medicine, Philadelphia, PA, USA; [2]Center for Outcomes Research, The Children's Hospital of Philadelphia, Philadelphia, PA, USA; [3]Senior Scholar, Leonard Davis Institute of Health Economics, University of Pennsylvania, Philadelphia, PA, USA; [4]The Wharton School, University of Pennsylvania, Philadelphia, PA, USA and [5]Leonard Davis Institute of Health Economics, University of Pennsylvania, Philadelphia, PA, USA

Objective: To determine the impact of state certificate of need programs (CON) on the number of hospitals with neonatal intensive care units (NICU) and the number of NICU beds.

Study Design: The presence of a CON program was verified from each state's department of health. Multivariable regression models determined the association between the absence of a CON program and each outcome after controlling for socioeconomic and demographic differences between states.

Result: A total of 30 states had CON programs that oversaw NICUs in 2008. Absence of such programs was associated with more hospitals with a NICU (Rate Ratio (RR) 2.06, 95% CI 1.74 to 2.45) and NICU beds (RR 1.96, 95% CI 1.89 to 2.03) compared with states with CON legislation, and increased all-infant mortality rates in states with a large metropolitan area.

Conclusion: There has been an erosion of CON programs that oversee NICUs. CON programs are associated with more efficient delivery of neonatal care.
Journal of Perinatology (2012) **32,** 39–44; doi:10.1038/jp.2011.47; published online 28 April 2011

Keywords: Hospital beds; regionalization of perinatal care

Introduction

Even with evidence that regionalized systems of perinatal care improve outcomes of premature infants,[1–4] data from multiple states suggest that an increasing number of prematurely born infants are delivered at hospitals with lower volume, lower-level neonatal intensive care units (NICUs).[5–8] One reason for this change in delivery hospital is the economic benefit that hospitals derive from constructing a NICU, regardless of its size or capabilities. Many obstetricians do not deliver at a hospital without a NICU on site, and those who do deliver at a hospital without NICU capabilities would have any high-risk delivery transferred to another hospital. Furthermore, hospitals extensively market their high-technology services such as NICUs to attract an entire family to use their hospital. These economic factors may induce hospitals to build NICUs, even when there may not be a need for these extra units at a regional level.[9]

There are mechanisms at the state level to limit the expansion of high-technology health care services such as neonatal intensive care. The most common mechanism is a certificate-of-need program (CON), initially developed in the 1970s. The overall goal of these programs is to contain healthcare costs by reducing expansions to the healthcare infrastructure. As a secondary goal, CON legislation was thought to improve the outcome of medical care by increasing the volume of patients at any one given hospital.[10–12] Although initially mandated by the Federal government through medicare payments, states now have the option to continue or disband their CON programs after the Federal government ended mandatory CON programs in 1987.

Although studies suggest that CON legislation reduces the number of adult acute-care hospital beds by 10 to 20%,[10] the effect of CON legislation on reducing the cost and outcomes of health care, principally for adult cardiac patients, shows conflicting results.[11,13–17] However, research on the impact of CON programs on the organization of pediatric health care services is limited. Neither the extent of CON legislation for NICUs nor the impact of such legislation on the supply of neonatal intensive care beds or statewide mortality rates has been examined. Moreover, the impact of CON legislation has not been explored in states with larger metropolitan areas that are likely to see a more rapid deregionalization of perinatal care. Thus, the goal of this project

Correspondence: Dr SA Lorch, Department of Pediatrics, The Children's Hospital of Philadelphia, Center for Outcomes Research, 3535 Market Street, Suite 1029, Philadelphia, PA 19104, USA.
E-mail: lorch@email.chop.edu
Received 27 December 2010; revised 6 March 2011; accepted 27 March 2011; published online 28 April 2011

was to (1) describe the extent of CON legislation in the United States regarding NICU expansion after elimination of Federal mandates for CON legislation in 1987; (2) determine the association of CON legislation on the number of NICUs and NICU beds; and (3) determine the association between CON legislation and statewide infant and very-low birth-weight (VLBW) mortality rates. All analyses will be carried out with and without adjustment for state characteristics, such as overall birth rate, rate of low-birth weight (LBW) and VLBW deliveries, degree of penetration by health maintenance organizations and educational status. We hypothesized that states with CON legislation will have fewer NICUs than states without CON legislation, with lower mortality rates. We also hypothesized that CON legislation would have the greatest effect on level II NICUs, which require the fewest resources to develop.

Methods

Assessment of CON legislation

On the basis of a survey of the state's website and telephone calls with each state's department of health, 37 states and the District of Columbia had CON legislation in place in 2009. To determine which states regulate NICUs with their CON program, administrators at each agency were directly contacted. Of these 37 states and the District of Columbia, 30 regulate the construction of NICUs through a CON program (Figure 1). No new CON programs were begun since the elimination of Federal mandates for CON legislation in 1987. Data were cross-referenced with data from the American Health Planning Association and the National Conference of State Legislatures.[18,19]

Outcome measures

The primary outcome measures were the number of NICUs and NICU beds in each state in 2008. This information was taken from the perinatal healthcare assessment survey published by the Perinatal Subgroup of the American Academy of Pediatrics.[20] In addition to total beds, we also calculated the total number of beds within level II NICUs and level III NICUs. The assessment survey also provided the NICU level at each hospital based on published American Academy of Pediatrics guidelines[21] (Table 1). We used these published guidelines to standardize the definition of NICU level between different states. As a measure of the outcome of perinatal care, all-infant mortality rates and mortality rates of VLBW infants (<1500 g at birth) and LBW infants (<2500 g at birth) from each state in 2005 were obtained from the National Center for Health Statistics.[22]

In multivariable analyses, we also included potential confounding variables for the number of hospitals and hospital beds in a state. These factors included the degree of penetration by

Table 1 Defined levels of neonatal intensive care units, 2001 section on perinatal pediatrics survey

Level	*Description of services*
I	Well baby nursery; neonatal resuscitation
II	Care of infants with birth weight >1500 g
IIIA	Restriction on type or duration of mechanical ventilation
IIIB	No restrictions on mechanical ventilation; no major surgeries
IIIC	Major surgery except for serious congenital heart anomalies or ECMO
IIID	All surgeries including congenital heart anomalies, requiring cardiopulmonary bypass and ECMO for medical conditions

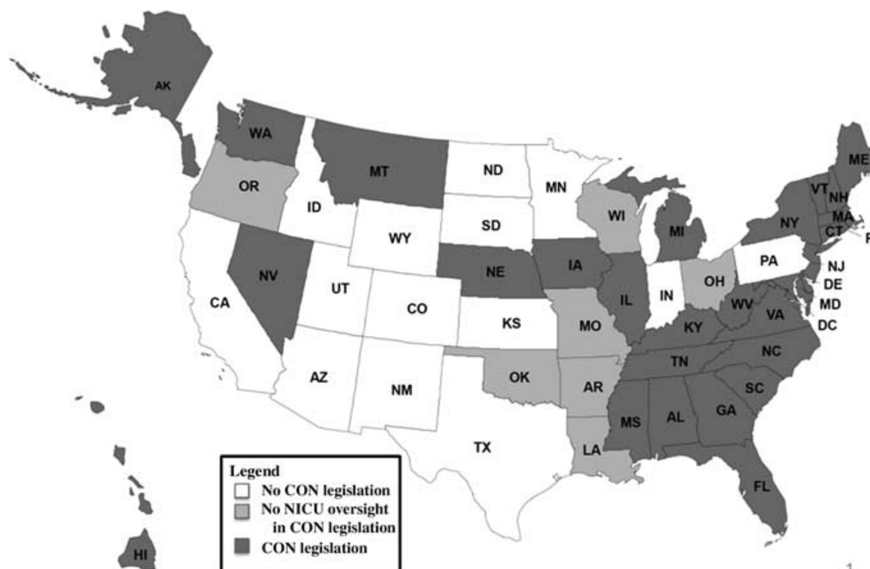

Figure 1 Graphical representation of the status of certificate of need legislation in United States, 2010. States in dark gray have certificate of need legislation in place that regulates the building of additional neonatal intensive care units (NICUs) and beds. States in white have no certificate of need legislation in place. States in light gray have certificate of need legislation currently in place, but do not regulate neonatal intensive care beds.

health maintenance organizations within a state, which may increase regionalization of perinatal care;[23] sociodemographic factors, such as the percentage of population with a high school education, the percentage of the population living below the poverty line and the percentage of births covered by Medicaid; and measures of the demand for neonatal services within a state, including overall birth rate and the percentage of births delivering either below 2500 g (LBW) or 1500 g (VLBW).

Data analysis

Because of the non-normal distribution of beds and number of NICUs in the data set, non-parametric ranksum tests compared variables in CON and non-CON states without adjusting for potential confounding variables. Multivariable poisson regression models were constructed to compare the independent effect of CON legislation on each of our number of bed and number of hospital outcome variables after controlling for these confounding variables. Poisson's models were used because many states had no or very few of these outcomes or zero-inflated outcomes data, with a concurrent rightward skew of the data. Linear regression models were used to determine any association between CON status and the three mortality rate figures listed above. Statistical significance was defined at the 5% level after controlling for multiple comparisons using the Bonferroni's correction. On the basis of 30 states having CON legislation, this study is powered to find a difference of 0.8 s.d. units in each mortality rate statistic. This difference translates to a change of 1.3 deaths/1000 infants, a 0.8% change in LBW mortality and a 2.6% change in VLBW mortality.

One potential issue with this analysis was that, in many smaller states with a small number of births, there are fewer economic incentives for expansion of neonatal care. For example, the state of Wyoming does not have a NICU in its state. However, many of these states may have CON programs to regulate NICUs. Including these smaller states may bias towards finding a nonsignificant result, if by building one NICU, the state has a very-high ratio of NICU beds to number of VLBW infants. To standardize the economic and geographic pressures for building additional neonatal beds and units, *a priori* we also carried out our analyses on a subgroup of states that had at least one metropolitan statistical area of one million residents or more in 2008, and between large and small states.

Results

Of the 37 states and the District of Columbia that have CON legislation, 30 regulate the development of NICUs (Figure 1). States with CON legislation tended to be east of the Mississippi, with large and small states represented in both groups.

Among all 50 states and the District of Columbia, the median number of hospitals with any NICU, any level III NICU or a level II nursery in states with CON legislation was similar to states without CON legislation (Table 2). However, when we only examined the states with at least one large metropolitan statistical area, those states with CON legislation had significantly fewer level IIIB hospitals (median 2, interquartile range (IQR) 0 to 7), level III hospitals (median 4.5, IQR 2 to 17) and hospitals with a NICU (median 4.5, IQR 3 to 18) compared with states without CON legislation (median 7 level IIIB hospitals, IQR 3 to 16; median 12 level III hospitals, IQR 7 to 29; median 14 NICU hospitals, IQR 7 to 35). These differences in NICU numbers also resulted in significantly fewer level IIIB, any level III and total number of NICU beds in states with CON legislation. Large metropolitan states with CON legislation had a median of 224 fewer NICU beds than those states without CON legislation. There were no statistically significant differences in all-infant, VLBW or LBW mortality rates between CON and non-CON states.

After controlling for differences in sociodemographic characteristics, birth rates and the degree of health maintenance organization penetration in each state, states without CON legislation had significantly more hospitals with a NICU (Rate Ratio (RR) 2.06, 95% CI 1.74 to 2.45) and total beds (RR 1.96, 95% CI 1.89 to 2.03) compared with states with CON legislation (Table 3). Level III NICUs made up these differences, as there was no statistically significant difference in the number of level II nurseries (RR 1.52, 95% CI 0.94 to 2.45) or beds (RR 1.18, 95% CI 0.99 to 1.39) between states with or without CON legislation.

The effects of CON legislation on the number of hospitals with NICUs and the number of NICU beds were larger when we examined only states with at least one large metropolitan area. Lack of CON legislation was associated with more hospitals with NICUs (RR 2.29, 95% CI 1.83 to 2.87) and more NICU beds (RR 2.36, 95% CI 2.26 to 2.47). The number of level III NICUs was 2.7 times higher in states without CON legislation, with the largest effect occurring in level IIIB hospitals (RR 3.21, 95% CI 2.17 to 4.73). Similarly, the effect of CON legislation also differed by a state's size (Table 3). The number of level III NICUs and beds were significantly higher in states without CON legislation, regardless of the state's size. However, the degree of the effect was larger in smaller states compared with larger states.

Mortality rates for VLBW or LBW infants were not significantly different between CON and non-CON states. However, for states with at least one large metropolitan area, states with CON legislation had significantly lower all infant mortality rates compared with states without CON legislation (0.54 fewer deaths/1000 births, 95% CI 0.02 to 1.06).

Discussion

Since the end of federally mandated CON legislation in 1987, 20 states have eliminated oversight of the building of additional NICUs or additional neonatal intensive care beds. These states are primarily in the West and Midwest and are widely diverse in size.

Table 2 Univariable differences in number of facilities and beds, by CON status

	All states		*States with a large metropolitan area*	
	CON (n = *31)*	*No CON* (n = *20)*	*CON* (n = *18)*	*No CON* (n = *14)*
Hospitals				
Level II	1 (0–2)	1 (0–3)	1 (0–2)	1.5 (0–3)
Level IIIA	1 (0–3)	1 (0–3)	0 (0–3)	1.5 (0–3)
Level IIIB	3 (0–6)	5 (1–8)	2 (0–7)*	7 (3–16)
Any level III	9 (3–15)	9 (6–27)	4.5 (2–17)*	12 (7–29)
All level II and III	11 (3–18)	11 (6–33)	4.5 (3–18)*	14 (7–35)
Beds				
Level II	5 (0–14)	8 (0–31)	6.5 (0–14)	8.5 (0–31)
Level IIIA	5 (0–29)	10 (0–28)	0 (0–24)	12 (0–28)
Level IIIB	60 (0–123)	89 (28–156)	33 (0–127)*	119 (73–254)
Any level III	227 (68–455)	304 (170–723)	113.5 (62–455)*	332 (225–738)
All level II and III	231 (76–464)	305 (198–754)	116 (68–464)*	339.5 (233–831)
Mortality rates				
All infants per 1000	7.06 (5.82–8.16)	6.63 (5.99–7.52)	7.27 (5.82–8.07)	6.7 (5.99–7.95)
Low-birth weight	5.8% (5.0%–6.4%)	5.9% (5.2%–6.3%)	5.9% (4.9%–6.4%)	6.2% (5.2%–6.3%)
Very-low birth weight	24.3% (21.5%–26.2%)	25.3% (22.7%–27.4%)	24.3% (22.5%–26.0%)	25.7% (22.7%–27.8%)

Abbreviation: CON, certificate of need.
Presented values are medians with interquartile ranges in brackets.
CON data taken from 2009 data collection; facility and bed data from 2008 AAP perinatal survey[20]; and mortality rates from 2005 National Center for Health Statistics.[22]
*$P<0.05$ by ranksum test.

In these 20 states without CON legislation, there are now twice as many hospitals with NICUs and almost twice as many NICU beds as in states with CON legislation. Contrary to our hypotheses, there are more hospitals with level III NICUs in states without CON legislation that have the capacity to care for the sickest premature infants, with the greatest initial costs. Even larger differences between CON and non-CON areas are seen in states with a metropolitan area of 1 000 000 people or greater, including a reduction in all infant mortality rates, and in smaller states. These results present for the first time both the current state of CON legislation for neonatal health care and evidence that CON legislation may be an effective tool to encouraging regionalization of neonatal intensive care, both from the number of hospitals delivering neonatal care and from reductions in mortality rates.

The impact of CON legislation on the supply and consequent outcome of health care has been investigated in adult medicine. CON programs were mandated at the federal level in 1974. Several studies before 1987 suggest that CON legislation reduced the number of hospital beds but did not affect other measures of health services investment.[24,25] More recent data after the elimination of Federal CON mandates demonstrate that states with CON programs have a 10 to 20% reduction in short-term acute care hospital beds.[10] The impact of these bed reductions on healthcare outcomes, however, is less well understood. Older studies suggest that increased regulation had either little effect on quality or increased mortality rates among adult hospital inpatients.[14,16] However, more recent data suggest that the mortality of Medicare beneficiaries in states with CON regulation is significantly lower, both before and after adjusting for medical risk.[26] Another recent study suggests that repealing CON legislation results in fewer procedures per hospital for the acute management of adult coronary disease with no permanent impact on mortality rates, using study designs that provide a less biased assessment of the impact of repealing CON legislation.[13] Our data are the first to study the effects of CON legislation on neonatal intensive care, and suggest that CON legislation has a larger effect on NICU bed supply than other studies of adult bed supply. Furthermore, our data suggest that there may be regional or state-specific effects that modify the association between CON legislation and NICU supply.

This work is also important because of recent data to suggest that regionalization of neonatal care is decreasing.[5–8]
For example, data from California found that the number of hospitals delivering high-level neonatal specialty care increased from 17 to 52 between 1990 and 1997. As a result, the percentage of total live births at regional perinatal centers declined from 16.9 to 11.7%, and the percentage of very LBW births at regional perinatal centers declined from 36.5 to 27.2%.[8] One reason for this shift is the economics of obstetrics care. Fees for the delivery of the infant are much higher than the fees for the provision of prenatal

Table 3 Multivariable analyses of CON legislation compared with non-CON legislation, rate ratios

	All states rate ratio, 95% CI	*States with a large metropolitan area*[a] rate ratio, 95% CI	*Large size states* (n = 20)[b] rate ratio, 95% CI	*Small size states* (n = 31)[b] rate ratio, 95% CI
Hospitals				
Level II	1.54 (0.94–2.45)	0.96 (0.53–1.72)	1.50 (0.70–3.23)	1.12 (0.61–2.05)
Level IIIA	1.69 (1.02–2.78)	2.82 (1.44–5.52)[c]	1.36 (0.65–2.85)	1.88 (1.05–3.35)
Level IIIB	2.13 (1.56–2.91)[c]	3.21 (2.17–4.73)[c]	0.98 (0.60–1.60)	3.00 (2.11–4.26)[c]
Any level III	2.19 (1.82–2.63)[c]	2.67 (2.10–3.42)[c]	1.46 (1.11–1.92)[c]	2.38 (1.91–2.96)[c]
All level II and III	2.06 (1.74–2.45)[c]	2.29 (1.83–2.87)[c]	1.48 (1.14–1.91)[c]	2.15 (1.75–2.64)[c]
Beds				
Level II	1.18 (0.99–1.39)	0.82 (0.67–1.01)	1.06 (0.81–1.38)	1.02 (0.83–1.26)
Level IIIA	1.82 (1.58–2.12)[c]	3.71 (2.92–4.47)[c]	1.64 (1.31–2.05)[c]	1.77 (1.49–2.11)[c]
Level IIIB	1.88 (1.75–2.02)[c]	2.91 (2.67–3.18)[c]	0.97 (0.87–1.08)	2.47 (2.27–2.68)[c]
Any level III	2.01 (1.94–2.09)[c]	2.52 (2.41–2.65)[c]	1.50 (1.42–1.59)[c]	2.04 (1.95–2.13)[c]
All level II and III	1.96 (1.89–2.03)[c]	2.36 (2.26–2.47)[c]	1.46 (1.38–1.53)[c]	1.99 (1.91–2.08)[c]
Mortality rates	Change, 95% CI	Change, 95% CI	Change, 95% CI	Change, 95% CI
Infant per 1000	0.25 (−0.14, 0.64)	0.54 (0.02, 1.06)[c]	0.07 (−0.64, 0.79)	0.46 (−0.17, 1.10)
Low-birth weight (%)	0.3 (−.02, 0.7)	0.4 (−0.2, 1.0)	0.4 (−0.3, 1.1)	0.3 (−0.3, 0.9)
Very-low birth weight (%)	1.6 (−0.4, 3.6)	1.3 (−1.6, 4.3)	2.5 (−1.3, 6.3)	0.6 (−2.2, 3.4)

All hospital and bed values are incident rate ratios, comparing states without CON legislation with those with CON legislation. Mortality rate values are percent change. 95% confidence intervals are presented in parenthesis. Models control for degree of health maintenance organization penetration, volume of deliveries <1500 and <2500 g, percent of births covered by Medicaid insurance, and poverty and education status in the state.
[a]States containing at least one metropolitan statistical area of one million residents or more in 2008.
[b]For geographical area, states were divided into the 20 largest states, each with an area over 69 900 square miles, and the remaining 31 states plus the District of Columbia.
[c]Values statistically significant at the $P<0.05$ level after application of the Bonferroni's correction for multiple comparisons.

care. Thus, many hospitals may be under economic pressure to open a specialty NICU to reduce the transfer of high-risk women to other hospitals.[9] The association we found suggests that CON legislation may counter these pressures to increase the supply of NICUs and beds in a given geographic area that result in higher costs.

CON legislation was associated with lower numbers of level III NICUs and beds, not lower level II units or beds that care for infants with birth weights over 1500 g. However, there were wide variations in the number of both level II and level III hospitals per state. This may occur because in some states there is additional legislation that constrains the ability of hospitals to build level III NICUs, such as 24-h neonatologist staffing requirements in Massachusetts.[27]

Some limitations to this work are similar to those of other studies of CON legislation. First, these data are only at the state level; no individual patient level data were available to improve risk adjustment of the mortality rate outcomes. The use of these data should not affect the evaluation of the supply of neonatal hospitals or neonatal beds, but the addition of patient-level data could change the association between the presence of CON legislation and perinatal outcomes, if there are large-scale, systematic differences in illness severity between states with CON legislation and those without. Given the population-based nature of these analyses, such a systematic difference in illness severity is unlikely. Moreover, this analysis does not account for patient preferences for where they receive their healthcare. Adult and obstetric patients tend to receive care at the closest hospital,[28,29] but the barriers to travel to hospitals further from home are not known for pediatric or high-risk obstetric patients. If patients demand high-technology care closer to home, then building more NICUs may provide benefits to the population even though the number of NICU beds is doubled. Finally, we cannot determine whether the repeal of CON legislation directly led to an increase in the number of NICU beds or hospitals. Because of the long time it takes to build NICU beds or hospitals, data are not available to apply various study design to assess this question, such as a difference-in-differences design. Moreover, there may be other factors in states that repealed CON legislation, such as the overall political belief system, that also resulted in an increased number of NICU beds. However, states that continue to have CON legislation vary widely in their political systems and overall economic health, including states from more interventional parts of the country such as the Northeast and states from more conservative areas such as the Southeast. Similar heterogeneity was seen in states without CON legislation. At the very least, our data suggest that the lack of CON legislation is associated with an expansion of NICU services.

In summary, we found that 20 states had eliminated their CON legislation for NICUs. The lack of CON legislation was associated with twice as many NICUs and NICU beds, primarily level III NICUs, after controlling for volume of VLBW and LBW infants and other characteristics of the economic health of the state. The effect seems to be greater in states with large metropolitan areas that provide the larger volume of deliveries that may stimulate further unchecked growth, and in smaller states. These data suggest that CON legislation could provide one method to balance economic pressures to increase the supply of neonatal beds in the United States.

Conflict of interest

The authors declare no conflict of interest.

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2013 Michigan Certificate of Need Annual Survey
Neonatal Intensive Care Services
Report 030

Facility Number	Facility Name	Hosp Group*	Number of Licen. Beds	Licensed Bed Days	Patient Days of Care	Discharges	Average Daily Census	Occupancy Rate	Length of Stay (Days)
63.0030	WILLIAM BEAUMONT HOSPITAL, ROYAL OAK	2	38	13,870	12,775	704	35.0	92.1%	18.1
63.0130	PROVIDENCE HOSPITAL AND MEDICAL CENTER	1	15	5,475	3,158	222	8.7	57.7%	14.2
63.0140	ST. JOSEPH MERCY OAKLAND HOSPITAL	2	29	10,585	4,744	276	13.0	44.8%	17.2
63.0160	WILLIAM BEAUMONT HOSPITAL, TROY	2	15	5,475	539	192	1.5	9.8%	2.8
74.0020	PORT HURON HOSPITAL	6	4	1,460	855	143	2.3	58.6%	6.0
81.0030	ST. JOSEPH MERCY ANN ARBOR HOSPITAL	5	15	5,475	5,100	1,044	14.0	93.2%	4.9
81.0060	UNIVERSITY OF MICHIGAN HOSPITALS	5	46	16,535	13,734	455	37.6	83.1%	30.2
82.0120	OAKWOOD HOSPITAL - DEARBORN	4	30	10,950	8,728	429	23.9	79.7%	20.3
83.0080	CHILDREN'S HOSPITAL OF MICHIGAN	1	45	16,425	9,817	1,036	26.9	59.8%	9.5
83.0190	HENRY FORD HOSPITAL	1	35	12,775	9,737	401	26.7	76.2%	24.3
83.0220	HARPER UNIVERSITY HOSPITAL	1	36	13,140	4,812	667	13.2	36.6%	7.2
83.0420	ST. JOHN HOSPITAL & MEDICAL CENTER	3	35	12,775	10,406	399	28.5	81.5%	26.1
83.0450	SINAI-GRACE HOSPITAL	1	20	7,300	4,517	327	12.4	61.9%	13.8
HSA 1: SOUTHEAST MICHIGAN		13 Facilities	363	132,240	88,922	6,295	243.6	67.2%	14.1
33.0060	EDWARD W SPARROW HOSPITAL	7	33	12,045	10,972	485	30.1	91.1%	22.6
HSA 2: MID-SOUTHERN		1 Facilities	33	12,045	10,972	485	30.1	91.1%	22.6
39.0020	BRONSON METHODIST HOSPITAL	10	45	16,425	14,350	685	39.3	87.4%	20.9
HSA 3: SOUTHWEST		1 Facilities	45	16,425	14,350	685	39.3	87.4%	20.9
41.0040	SPECTRUM HEALTH BUTTERWORTH HOSPITAL	14	72	26,280	26,280	1,268	72.0	100.0%	20.7
41.0080	MERCY HEALTH SAINT MARY'S	14	15	5,475	3,364	161	9.2	61.4%	20.9
HSA 4: WEST MICHIGAN		2 Facilities	87	31,755	29,644	1,429	81.2	93.4%	20.7
25.0040	HURLEY MEDICAL CENTER	19	44	16,060	10,112	687	27.7	63.0%	14.7
HSA 5: GENESEE-LAPEER-SHIAWASSEE		1 Facilities	44	16,060	10,112	687	27.7	63.0%	14.7
73.0061	COVENANT MEDICAL CENTER - HARRISON	20	40	14,600	11,212	618	30.7	76.8%	18.1
HSA 6: EAST CENTRAL		1 Facilities	40	14,600	11,212	618	30.7	76.8%	18.1
28.0010	MUNSON MEDICAL CENTER	24	12	4,380	902	291	2.5	20.6%	3.1
HSA 7: NORTHERN LOWER		1 Facilities	12	4,380	902	291	2.5	20.6%	3.1
52.0050	MARQUETTE GENERAL HOSPITAL	28	10	3,650	1,965	28	5.4	53.8%	70.2
HSA 8: UPPER PENINSULA		1 Facilities	10	3,650	1,965	28	5.4	53.8%	70.2

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

*Hospitals not placed in a Hospital Group are noted with NG (No Group).

2013 Michigan Certificate of Need Annual Survey
Neonatal Intensive Care Services
Report 030

Facility Number	Facility Name	Hosp Group*	Number of Licen. Beds	Licensed Bed Days	Patient Days of Care	Discharges	Average Daily Census	Occupancy Rate	Length of Stay (Days)
State Total	**21 Facilities**		**634**	**231,155**	**168,079**	**10,518**	**460.5**	**72.7%**	**16.0**

Licensed bed counts are listed as of December 31, 2013 from the Licensing and Certification Division, BHS, LARA. The calculations for licensed bed days account for the adding and delicensing of beds throughout the calendar year based on MDCH records.

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

*Hospitals not placed in a Hospital Group are noted with NG (No Group).

From:	DoNotReply@michigan.gov
To:	MDCH-ConWebTeam
Subject:	2016 CON Standards Public Comment (ContentID - 306550)
Date:	Tuesday, October 20, 2015 10:33:17 AM
Attachments:	UMS_UESWL_2016_Public_Comment.pdf

1. Name: Jorgen Madsen
2. Organization: United Medical Systems
3. Phone: 8005169425
4. Email: JMadsen@ums-usa.com
5. Standards: UESWL
6._Testimony: See attached letter.

Content-Length: 89934

October 19, 2015

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

Re: CON Standards for UESWL Services

Dear Chairman Keshishian,

Thank you for the opportunity to provide comments regarding the Certificate of Need Standards for Urinary Extracorporeal Shock Wave Lithotripsy Services (UESWL). I understand that as part of this review, the CON Commission is tasked with evaluating whether or not each covered clinical service should remain regulated under the Certificate of Need program. As the CEO of United Medical Systems (DE), Inc. (UMS), minority owner of Great Lakes Lithotripsy, I am writing to encourage the continued regulation of UESWL services and to provide you with support for doing so.

Michigan's CON standards for UESWL services have created an exceptional environment to ensuring broad access, at a relatively low cost, with exceptional quality. UMS has been providing transportable lithotripsy services in the United States since 1998 and in Michigan since 2001. In Michigan, UMS owns and manages four mobile lithotripsy routes (7 units total) through several subsidiaries. We are finding in Michigan that capacity and demand are in very good balance, resulting in great access with stable pricing.

Our units are capable of providing 12 lithotripsy procedures per day, but are averaging only 5-6 per day. In addition, there are still days of service available on our routes, so there is capacity to add additional service sites or additional days to existing sites. Bottom line, there is still capacity to provide more access, but enough to maintain competitive pricing and excellent quality. In fact, we have had zero reported cases of adverse events in the Great Lakes Lithotripsy service network in the past 3 years since these standards were last reviewed.

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. In fact, 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 the same highly experienced technologist operating the equipment. The same holds true for ambulatory surgery facilities, which make up 26% of all host sites in the State.

1700 West Park Drive, Suite 410
Westborough, MA 01581
Phone: 508-870-6565
Fax: 508-870-0682
www.ums-usa.com

The current system encourages better utilization of existing equipment, prevents a capital equipment arms race among providers, and concentrates procedures in a way that allows for high volume technologists to provide the highest quality care to the citizens of Michigan. And all of these attributes allow mobile providers to keep costs under control and offer very competitive rates to all facilities in the State.

For all of these reasons, and more, we support the continued regulation of UESWL services under Certificate of Need in Michigan as well as the current standards. Please feel free to contact me directly with any questions at 1-800-516-9425.

Respectfully,

Jorgen Madsen
CEO