Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Tuesday, October 23, 2012 12:27 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)

1. Name: Anny Arana
2. Organization: Allegiance Health
3. Phone: 517-788-4831
4. Email: anny.arana@allegiancehealth.org 5. Standards: CT 6. Testimony: After reviewing the 2011 Annual Survey Report volumes and the current CT Standards, we would like the CT volume requirements and conversion factors to be reviewed for updates. With new technology constantly evolving, we are able to scan more patients per CT machine. As an example, average scan times for patients 10 years ago have decreased from 1 hour to an average of 15-20 minutes. In addition, we would like to add language to the "special needs patient" definition to include trauma patients.

7. Testimony:

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 3:50 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)

1. Name: Sean Gehle
2. Organization: Ascension Health - Michigan 3. Phone: 517-482-1422 4. Email: sean.gehle@stjohn.org 5. Standards: AA 6. Testimony: Ascension Health - Michigan supports continued regulation of Air Ambulance services and does not recommend any changes to the current standards.
7. Testimony:

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 3:46 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)

1. Name: Sean Gehle
2. Organization: Ascension Health - Michigan 3. Phone: 517-482-1422 4. Email: sean.gehle@stjohn.org 5. Standards: Litho
6. Testimony: Ascension Health - Michigan supports the continued regulation of Urinary Extracorporeal Shock Wave Lithotripsy Services and does not recommend any changes to the current standards.
7. Testimony:

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 3:46 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)

1. Name: Sean Gehle
2. Organization: Ascension Health - Michigan 3. Phone: 517-482-1422 4. Email: sean.gehle@stjohn.org 5. Standards: Litho
6. Testimony: Ascension Health - Michigan supports the continued regulation of Urinary Extracorporeal Shock Wave Lithotripsy Services and does not recommend any changes to the current standards.
7. Testimony:

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 2:39 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: BeaumontResponseToReviewStandards.pdf

1. Name: Patrick O'Donovan
2. Organization: Beaumont Health System 3. Phone: 248-551-6406 4. Email: podonovan@beaumont.edu 6. Testimony:

Content-Length: 50614

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 2:39 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: BeaumontResponseToReviewStandards.pdf

1. Name: Patrick O'Donovan
2. Organization: Beaumont Health System 3. Phone: 248-551-6406 4. Email: podonovan@beaumont.edu 6. Testimony:

Content-Length: 50614

Beaumont® | HEALTH SYSTEM

October 24, 2012

Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Certificate of Need Commission:

This letter is written as formal testimony pertaining to the C.O.N. Review Standards for Computed Tomography (CT) Services, Neonatal Intensive Care Services/Beds (NICU) Services, Nursing Home and HLTCU Beds (NH) Services and Lithotripsy (Litho) Services, which are scheduled for review in 2013.

Computed Tomography (CT) Services
Beaumont supports the continued regulation of computed tomography (CT) services. No specific changes to these standards are recommended at this time.

Neonatal Intensive Care Services/Beds (NICU) Services
Beaumont supports the continued regulation of neonatal intensive care services/beds. No specific changes to these standards are recommended at this time.

Nursing Home and HLTCU Beds (NH) Services
Beaumont supports the continued regulation of nursing home and HLTCU beds (NH) and services. No specific changes to these standards are recommended at this time.

Lithotripsy Services (Litho) Standards
Beaumont supports the continued regulation of lithotripsy services. Beaumont recommends that the Commission consider reducing the volume requirement for expanding the number of lithotripsy machines on a given route. The current level of 1800 procedures per machine per year is unrealistically high and inhibits expansion by mobile lithotripsy providers to adequately provide services for underserved areas. Without adequate lithotripsy access, patients with kidney stones may have to undergo invasive ureteroscopy procedures, which are more risky and more expensive than noninvasive UESWL procedures.

Thank you for the opportunity to provide comment on these C.O.N. Review Standards.

Sincerely,

Patrick O'Donovan
Vice President, Planning
Beaumont Health System

3711 West Thirteen Mile Road
Royal Oak, Michigan 48073-6769

Beaumont® | HEALTH SYSTEM

October 24, 2012

Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Certificate of Need Commission:

This letter is written as formal testimony pertaining to the C.O.N. Review Standards for Computed Tomography (CT) Services, Neonatal Intensive Care Services/Beds (NICU) Services, Nursing Home and HLTCU Beds (NH) Services and Lithotripsy (Litho) Services, which are scheduled for review in 2013.

Computed Tomography (CT) Services
Beaumont supports the continued regulation of computed tomography (CT) services. No specific changes to these standards are recommended at this time.

Neonatal Intensive Care Services/Beds (NICU) Services
Beaumont supports the continued regulation of neonatal intensive care services/beds. No specific changes to these standards are recommended at this time.

Nursing Home and HLTCU Beds (NH) Services
Beaumont supports the continued regulation of nursing home and HLTCU beds (NH) and services. No specific changes to these standards are recommended at this time.

Lithotripsy Services (Litho) Standards
Beaumont supports the continued regulation of lithotripsy services. Beaumont recommends that the Commission consider reducing the volume requirement for expanding the number of lithotripsy machines on a given route. The current level of 1800 procedures per machine per year is unrealistically high and inhibits expansion by mobile lithotripsy providers to adequately provide services for underserved areas. Without adequate lithotripsy access, patients with kidney stones may have to undergo invasive ureteroscopy procedures, which are more risky and more expensive than noninvasive UESWL procedures.

Thank you for the opportunity to provide comment on these C.O.N. Review Standards.

Sincerely,

Patrick O'Donovan
Vice President, Planning
Beaumont Health System

3711 West Thirteen Mile Road
Royal Oak, Michigan 48073-6769

Ciena Healthcare Comments
to
CON Review Standards for Nursing Homes
October 24, 2012

Thank you for the opportunity to comment on the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds. The Ciena Healthcare group consists of 34 skilled nursing facilities in the state of Michigan. In the past seven years, we have built seven new skilled facilities in the state and are close to completing construction of two more facilities. We have been a frequent user of the CON process and standards and we have a unique and practical perspective on the impacts of the standards on the skilled nursing industry.

We strongly believe the CON standards should permit operators to meet the ever changing demand of our customers, the residents. The pace of change in long term care has never been greater as our facilities provide a spectrum of care that has changed since the last Standards Advisory Committee was convened to review the standards. Healthcare reform and the aging baby boomer population are demanding more dynamic living environments and services that closer resemble a hotel than the nursing homes of just ten years ago. The CON standards should not be an obstacle to providers to provide to consumers what they require within the realms of the bed inventories available in a planning area.

We recommend simplifying the CON standards to allow healthcare providers flexibility to build, replace and relocate aging facilities to meet the demands of the skilled nursing consumer. We would therefore recommend that at the minimum, a workgroup be formed or a Standards Advisory Committee (SAC) be established to review the standards and make recommendations that reflect the current state of the rapidly changing skilled nursing environment.

Below is a brief summary of recommended changes:

Section 1 Applicability

No comment

Section 2 Definitions

Replacement Zone – Remove the concept of the replacement zone from the CON standards. Bed needs are based on county populations. Operators should have flexibility to build new or replacement facilities in the County planning area based on the needed be supply for the planning area. This would allow providers to be most responsible to customer needs. The replacement zone concept limits the ability to build or replace nursing homes in areas where there is a demand within the county.

Section 3 and 4 Determination of Supply and Bed Need

The current bed should be updated to reflect the 2010 census data to provide for best demographic information available.

Section 5 Modification of the age specific use rates

No comment

Section 6 Requirements for approval to increase beds

Section 2 (d)(i). Delete the limitation in this section that a portion of a new design project may increase the beds in the planning area only if a portion of an existing nursing home is replaced within the replacement zone. The replacement zone restriction here makes no practical sense and provide little if any incentive for an existing nursing home to take advantage of this section due to the replacement zone restriction.

Section 7 Requirement for approval to relocate beds

Modification of the current relocation of beds standard provides an excellent opportunity for Michigan to allow nursing home providers to relocate beds into new construction projects to build facilities that meet the needs of today's long and short term residents and their increasingly rising expectations for hotel-like living environments and services.

The current standards have arbitrary placed restrictions on limiting the relocation to 50% of the beds and once every 7 years. There is no logical reason for these restrictions and the relocation option has proven to be a valuabnle tool to create newly constructed facilities. We recommend removal of the 50% and 7 year restrictions Furthermore, we recommend the relocation standard to be revised so that beds can be relocated from both an existing nursing home or approved project to be located to both an existing nursing home or approved project. This change will result in maximizing the replacement of old physical plants to newly constructed facilities that will offer Michigan citizens access to state of the art facilities.

An out of the box concept that would encourage providers to downsize their facilities to reduce 3 or more bed wards or convert to all private rooms would be to allow such a provider to "bank" the beds they desire to remove from an existing facility for a period of 2-3 years so they can decide what to do with the beds such as file a relocation or replacement CON. Many providers want to reduce the beds at their facilty but don't want to lose the beds or don't immediately have a plan how to use the excess beds. Providing providers with a time period to keep the beds and decide how to utilize them will greatly encourage immediate downsizing of facilities.

Section 8 Requirements for approval to replace beds

The current replacement standards do not encourage replacement facilities because only replacements within the replacement zone are not restricted. Providers currently cannot meet the needs of a particular planning area because they are limited to the replacement zone.

We recommend that providers be given maximum flexibility to replace existing facilities within the County planning areas and remove the replacement zone concept. Remove the barrier that limit new construction and capital investments in our state and a building boom will occur. Although the current standards encourages replacement buildings to follow the new design model, this concept is outdated because the consumer market for nursing home services now demands private rooms and bathrooms and new facilities being built now must have these features to attract residents.

Ciena also supports the recommendation from the Healthcare Association of Michigan to (a) allow replacement CONs to only file a Letter of Intent which would be granted a waiver from the full CON application process and (b) allow providers in a replacement facility to combine other existing facilities within the planning area.

Section 9 Requirements for approval to acquire or renew lease

Delete the requirement that all new acquisitions that require a CON must participate in a quality improvement program and provide annual reporting to the state and ombudsman. This is an unnecessary and burdensome requirement that seeks to place an additional licensing requirement on providers. The licensing and Medicare/Medicaid survey process sufficiently addressees poor performing facilities through the enforcement process.

Section 3 requires new CONs for all real estate lease renewals. This requirements is unnecessary and burdensome when an existing lease is being renewed. It is recommended renewal leases be exempted from the CON standards.

Section 10 Comparative Review

The current point assignments under this section seem to provide little to no differentiation for applicants other than whether a facility has 100% private beds or is located near a bus stop. The comparative standards do not reflect sound public policy and should be reviewed. Our specific recommendations:

- Remove from Section 10(5) the 5 point advantage that an existing provider has with a culture change program over a new applicant who will implement a culture change model. This is unfair and provides large unnecessary point advantage to an existing facility.
- Increase the points awarded for use of technology for a project. We suggest 5 points for utilization of electronic health records, 2 points for wireless internet and 2 points for internet cafes/stations for residents.
- Remove the category that awards points for a project accessible to public transportation. This criterion unfairly favors urban to rural or suburban project locations within the same planning area which is an unattended impact of this criteria.

Section 11 Project delivery requirements

No comment

Section 12 Department inventory of beds

The inventory should reflect the recalculation of the bed need based on the 2010 census data.

Section 13 Wayne county planning areas

No comment

Section 14 Health Service Areas

No comment

Section 15 Effect on prior CON review standards, comparative review

Section 152)(b). We recommend changing so that replacement of a nursing home within the planning area is exempt from comparative review. It is absurd that a provider who seeks to replace a nursing home would be subject to comparative review. In the alternative, the existing two mile radius exemption should be changed to 3 miles to coincide with the replacement zone (although we advocate elimination of the replacement zone concept entirely)

CON Proposed Rule Changes in Administrative Law Process

When CON applications are filed, applications must speculate as to the available of beds, likelihood of comparative review and success the project will receive the most points. It is thus not practical for applications to purchase property before a CON is approved. Therefore, a provider should be able to relocate, by amendment to the CON, application, an approved project before construction to another location under certain circumstances that cause the project implementation at the specific site to be

impractical. Examples of this would be when a proposed sight is longer available to be purchased or cannot be purchased for the buyer's anticipated purchase price, where local ordinances and ruling make development impractical, where environmental issues arise that adversely impact the project, etc.

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 1:07 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: Comments_to_CON_standards_102412.pdf

1. Name: David G. Stobb
2. Organization: Ciena Healthcare
3. Phone: 2486322048
4. Email: dstobb@cienahmi.com
5. Standards: NH
6. Testimony:

Content-Length: 221097

Ciena Healthcare Comments
to
CON Review Standards for Nursing Homes
October 24, 2012

Thank you for the opportunity to comment on the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds. The Ciena Healthcare group consists of 34 skilled nursing facilities in the state of Michigan. In the past seven years, we have built seven new skilled facilities in the state and are close to completing construction of two more facilities. We have been a frequent user of the CON process and standards and we have a unique and practical perspective on the impacts of the standards on the skilled nursing industry.

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We recommend simplifying the CON standards to allow healthcare providers flexibility to build, replace and relocate aging facilities to meet the demands of the skilled nursing consumer. We would therefore recommend that at the minimum, a workgroup be formed or a Standards Advisory Committee (SAC) be established to review the standards and make recommendations that reflect the current state of the rapidly changing skilled nursing environment.

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No comment

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The current bed should be updated to reflect the 2010 census data to provide for best demographic information available.

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Section 8 Requirements for approval to replace beds

The current replacement standards do not encourage replacement facilities because only replacements within the replacement zone are not restricted. Providers currently cannot meet the needs of a particular planning area because they are limited to the replacement zone.

We recommend that providers be given maximum flexibility to replace existing facilities within the County planning areas and remove the replacement zone concept. Remove the barrier that limit new construction and capital investments in our state and a building boom will occur. Although the current standards encourages replacement buildings to follow the new design model, this concept is outdated because the consumer market for nursing home services now demands private rooms and bathrooms and new facilities being built now must have these features to attract residents.

Ciena also supports the recommendation from the Healthcare Association of Michigan to (a) allow replacement CONs to only file a Letter of Intent which would be granted a waiver from the full CON application process and (b) allow providers in a replacement facility to combine other existing facilities within the planning area.

Section 9 Requirements for approval to acquire or renew lease

Delete the requirement that all new acquisitions that require a CON must participate in a quality improvement program and provide annual reporting to the state and ombudsman. This is an unnecessary and burdensome requirement that seeks to place an additional licensing requirement on providers. The licensing and Medicare/Medicaid survey process sufficiently addressees poor performing facilities through the enforcement process.

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- Increase the points awarded for use of technology for a project. We suggest 5 points for utilization of electronic health records, 2 points for wireless internet and 2 points for internet cafes/stations for residents.
- Remove the category that awards points for a project accessible to public transportation. This criterion unfairly favors urban to rural or suburban project locations within the same planning area which is an unattended impact of this criteria.

Section 11 Project delivery requirements

No comment

Section 12 Department inventory of beds

The inventory should reflect the recalculation of the bed need based on the 2010 census data.

Section 13 Wayne county planning areas

No comment

Section 14 Health Service Areas

No comment

Section 15 Effect on prior CON review standards, comparative review

Section 152)(b). We recommend changing so that replacement of a nursing home within the planning area is exempt from comparative review. It is absurd that a provider who seeks to replace a nursing home would be subject to comparative review. In the alternative, the existing two mile radius exemption should be changed to 3 miles to coincide with the replacement zone (although we advocate elimination of the replacement zone concept entirely)

CON Proposed Rule Changes in Administrative Law Process

When CON applications are filed, applications must speculate as to the available of beds, likelihood of comparative review and success the project will receive the most points. It is thus not practical for applications to purchase property before a CON is approved. Therefore, a provider should be able to relocate, by amendment to the CON, application, an approved project before construction to another location under certain circumstances that cause the project implementation at the specific site to be

impractical. Examples of this would be when a proposed sight is longer available to be purchased or cannot be purchased for the buyer's anticipated purchase price, where local ordinances and ruling make development impractical, where environmental issues arise that adversely impact the project, etc.

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 10:32 AM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)

1. Name: J. Mark Greene
2. Organization: Extendicare Health Services 3. Phone: 262-968-3171 4. Email: jgreene@extendicare.com 5. Standards: NH 6. Testimony: Thank you for the opportunity to comment on the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds. Extendicare, as one of the largest providers in Michigan, has severally concerns with the current CON standards and would recommend at least a workgroup be formed or a Standards Advisory Committee (SAC) be established.

While the current standards have seen minor changes over the last few years following the major over haul from the 2009 SAC. Now seems to be the time to once again review the standards and make needed changes to have a better system as we go forward.

Extendicare's concerns are noted below.

Section (2)(1)(d) Since the section seems to require an annual survey, update to define a specific year in recent history or simply say the most current survey. Eliminate the ancient reference.
Section (3) general comment, we believe that all bed need should be updated to reflect 2010 census statistics.

Section (3)(1)(b) Should the cohorts be re accessed? We have made 65 a magical year perhaps for the future the cohorts need to be realigned. For LTC make it 0 - 21, 22-67 68-80 then 80+ or perhaps someone has looked at age relevant data for utilization for better cohorts.

Section 6 (1)(a) I think the 14% or 5 maximum may penalize certain larger providers that operate in states with aggressive survey agencies. Why not drop the 5 maximum as 5 is significantly different if you have 40 or 400.
Section 6 (1)(a) vii, Exclude QAAP from the percentage or 5 rule and simply say if no pay no play. Otherwise this encourages providers not to pay.
Section 6 (1)(d) ii , The occupancy exception seems to favor CCRC, I would add that 51 percent of admissions must be from the public and not the related complex. In addition, create an exception if there is a need for specialty beds for vents or bariatric patients. Make licensure contingent upon structure specifically built for this need.
Section 6, iii (A) update to 2010 census

Section 7 Requirement for approval to relocate beds -- Relocation of beds was included in the standards at the time of the prior year's SAC. This policy has been beneficial in providing access to care where needed and in a financially cost efficient approach. The standard contains some very restrictive and rather arbitrary requirements such as only 50% of the beds and once every 7 years. My understanding is that these limiters were initially added in the standards to enable the relocation of beds to be tested. Both of these limitations need to be reviewed and either eliminated or adjusted upward to better meet the care needs of Michigan.

Section 8 Requirements for approval to replace beds -- Michigan has always encouraged nursing home to not only upgrade their structures but to totally replace facilities. Filing of a full CON for a total replacement is a redundant process as a CON has already been granted for the licensed beds. Extendicare recommends that total replacement facilities be required to only file a Letter of Intent which would be granted a waiver from the full CON application process. This would reduce the cost and workload for both the state and providers. We would also request that a provider with a larger facility be able to split the facility into two smaller centers serving the same planning area or to

combine two older facilities into a single structure. Such an approach gives providers better opportunity to meet the needs of the service area and maximize delivery efficiency.

Section 10 Comparative Review -- The current point assignments under this section seem to provide little to no differentiation for applicants. This section needs to completely reviewed and adjusted to meet the changing landscape of long-term care services. Potential changes would include: no points for sprinklering since it is a federal mandate as of August 13, 2013; review changes in Medicaid participation as more of these providers are serving the sub-acute care needs; points for day one Medicaid admissions, including patients admitted as dual eligible, points for downsizing wards; and greater recognition of technology utilized in long-term care.

J. Mark Greene, Conslutant
Extendicare Health Services, Inc.

7. Testimony:

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 4:51 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)

1. Name: Sean Gehle
2. Organization: Genesys Health system
3. Phone: 517-482-1422
4. Email: sean.gehle@stjohn.org
5. Standards: NH
6. Testimony: Genesys Health system supports continued regulation of Nursing Home and HLTCU Beds and with regard to the Special Population Pool Bed replacement and relocation recommends expanding the replacement zone beyond the current mile radius limitation.
7. Testimony:

HCAM Comments CON Standards

Thank you for the opportunity to comment on the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds. The Health Care Association of Michigan represents more than 290 nursing facilities, county medical care facilities and hospital long-term care units across the state. As the largest association representing this segment of providers, we have several concerns with the current CON standards and would recommend at least a workgroup be formed or a Standards Advisory Committee (SAC) be established. The goal of any changes to the standards should always keep in mind the impact on the consumer of the services. Each change should answer the question: How does will this change improve the quality of care and life for the person's served in these settings?

The current standards have seen minor changes over the last few years following a major over haul from the 2009 SAC. Now seems to be the time to once again review the standards and make needed changes to have a better system as we go forward.

HCAM's areas of concern range from technical issues to adjusting the comparative review section. Below is an outline of our primary concerns.

Section 1 Applicability

No comment

Section 2 Definitions

Planning area – reference to section 12 should be to section 13

Section 3 and 4 Determination of Supply and Bed Need

HCAM strongly recommends that the current Bed Need be updated to reflect the 2010 census data to provide for the changes in demographics.

Section 5 Modification of the age specific use rates

No comment

Section 6 Requirements for approval to increase beds

Part 1. (vi) (d) (ii) Exception to the number of beds approved for high occupancy. The threshold is extremely high considering the current environment and is inconsistent within the section see part 1 (vi) (iii) (B). The first percentage is 94% and the second percentage is 92%, it seems like they should be consistent at 92%.

Section 7 Requirement for approval to relocate beds

Relocation of beds was included in the standards at the time of the prior year's SAC. This policy has been beneficial in providing access to care where needed and in a financially cost efficient approach. Although the standard contains some very restrictive and rather arbitrary requirements, such as only 50% of the beds to be relocated, and then once every 7 years, these limiters were initially included

in the standards to enable the process of relocation of beds to be tested. The process has had some positive effect on the efficient use of financial and physical resources; however, the limits have restricted some projects that would have had a beneficial impact on the health care system. Both of these constraints need to be reviewed and either eliminated or adjusted upward to better meet the care needs of our citizens.

Section 8 Requirements for approval to replace beds

Michigan has always encouraged nursing home and HLTCU providers to not only upgrade their structures but to totally replace facilities. While updating of the facility is possible, for some a total facility replacement is the only appropriate renovation. HCAM would like to recommend that total replacement facilities on their current site or within the planning area, be required to only file a Letter of Intent which would be granted a waiver from the full CON application process. HCAM does not recall any total replacement facility not being approved, so why go through the full process. It not only saves costs, it would reduce the workload for the CON staff. This change would be for a replacement that does not include an increase in beds.

Where more extensive review is warranted, the fact that the beds to be replaced are completely within the control of the applicant, and do not come from any pool of unclaimed beds, it suggests against subjecting such projects to the comparative review schedule, regardless of where they may be replaced. HCAM supports modifying this section to remove this kind of project from comparative review.

Another concern with replacement facilities is the desire by providers to combine two old facilities into one new structure. The current interpretation is that a replacement creates one new site under the replacing facility's licensure and upon completion, receives a separate license; however, the current interpretation does not allow replacing two facilities into a single site under a new single licensure. It seems to be cost efficient to create one structure and not require two separate structures that are next to each other. This limitation suppresses the replacement of older buildings with modern buildings within the population of existing beds.

Section 9 Requirements for approval to acquire or renew lease

It is unclear why a renewal of a lease arrangement is included with an acquisition of an existing facility. HCAM would recommend that renewal of an existing lease with the same parties be granted a waiver under CON upon the filing of a Letter of Intent. Once again it will save on costs and CON staff time.

Section 10 Comparative Review

The current point assignments under this section seem to provide little to no differentiation for applicants. Many reviews are resolved by small point margins. A comprehensive and coordinated revamping of this section needs to be done.

Potential changes would include: no points for sprinklering since it is a federal mandate as of August 13, 2013; review changes in Medicaid participation as more of these providers are serving the sub-acute care needs; points for downsizing wards; and greater recognition of technology utilized in long-term care.

In addition, this section overtly favors expansion of older, existing facilities over the creation of new, modern buildings. To gain that comparative advantage, the existing facility simply had to be without cited plant violations; beyond that, there is no weight given to the design and condition of the portion of the building that will remain in service. It is not clear that additions to old facilities better serve to reduce cost, increase access or improve quality, when compared with new buildings. HCAM supports the review and correction of this inherent preference.

Section 11 Project delivery requirements

No comment

Section 12 Department inventory of beds

The inventory should reflect the recalculation of the bed need based on the 2010 census data.

Section 13 Wayne county planning areas

No comment

Section 14 Health Service Areas

No comment

Addendum for Special Population Groups

The criteria for each group contained in the addendum should be reviewed compared to the creation of these beds for their special purpose. Are the criteria to stringent or too lenient? Why have so few of these beds actually been made available to deliver the care? Do they address the right care area?

Technical Changes

Many sections of these standards refer to the quality requirements which include the outstanding obligation for the Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP). The standard should state it refers to these obligations that have due dates at least 60 days prior to the application filing so that the applicant is considered current in payment. This section may also want to address the payment of either a QAAP or CMP liability for a non-comparative review project as a condition of the approved project.

CON Proposed Rule Changes in Administrative Law Process

One issue that is in the proposed administrative rules process needs to be brought forward. The issue is a change in location of the nursing home after

CON approval has been granted. Currently if the initially approved proposed site is no longer available for constructing the nursing home a new CON is required to build. This should be amended to state a new location can be granted if the applicant can demonstrate the original site is no longer available because of unforeseen reasons and a new site within the planning area and, if applicable, the 3 mile rule is available then a new CON is not required. The approved CON would be amended to disclose the new location.

Documentation on Average Citations

The standards have a quality measure related to the average citations at “D” or above which is reported on the website. The data from July 2011 to March 2012 appears to be wrong. The average number of these citations for the quarters prior to July 2011 was about 7.7, the subsequent quarters is 1.8. This much of a change is unrealistic, the calculation needs to be reviewed and corrected.

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 1:47 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: CONCommentsNFHLTCUforHCAMOct_24.doc

1. Name: Pat Anderson
2. Organization: Health Care Association of Michigan 3. Phone: 517-627-1561 4. Email: patanderson@hcam.org 5. Standards: NH 6. Testimony: Comments are attached. Thank you.

Content-Length: 50844

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 2:27 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: HCRMANORCAREcommentsNursingHomeStandards.doc

1. Name: Lisa Rosenthal
2. Organization: HCR ManorCare
3. Phone: (240) 453-8569
4. Email: lrosenthal@hcr-manorcare.com
5. Standards: NH
6. Testimony: see attached file

Content-Length: 154549

Comments on CON Review Standards for Nursing ome and Hospital Long-Term Care Unit Beds
Submitted During Public Comment Period
October 24, 2012

HCR Manor Care, Inc., on behalf of its subsidiary operating companies in Michigan, ("HCR") submits the following comments regarding the CON Review Standards for Nursing Home and Hospital Long-Term Care Unit Beds. HCR ManorCare is a national long-term care provider with 28 nursing home facilities in Michigan. These comments address the importance of re-opening the Standards for review at the January 2013 Commission Meeting.

HCR appreciates the Commission's efforts to implement revised Nursing Home Home Standards in 2010, but believes that further revisions are necessary in order to recognize the changes that have occurred in the health care industry since 2010. Under the current Standards, the net effect of the Comparative Review Criteria results in minimal differentiation among competing CON applications. The current Standards do not therefore assure that Michigan residents receive quality, innovative and state of the art nursing home services.

In addition to considering revisions to the Comparative Review Criteria, we recommend the following:

- Sections 4 and 5/ Bed Need: We support an update the Nursing Home bed need projections using base year data from the 2010 Nursing Home Survey and the 2010 United States Census data, applied to population projections. This will ensure that the Nursing Home bed need projections respond to recent Michigan nursing home utilization and reflect changes in Michigan planning area population changes, thus ensuring access to vital nursing home services.
- Section 6 / High Occupancy Provision: We support limited revisions to the high occupancy language. The intent of the June 2008 Standard revisions was to allow successful nursing homes to get a small number of additional beds without being tied to utilization of other nursing homes in the planning area. This concept had widespread support as it would allow consumers to select quality nursing homes and to increase the

competition faced by poor performing facilities. However, Section 6(1)(d)(ii)(A) failed to eliminate the linkage between the number of beds available under the high occupancy language and the occupancy rates of the other nursing homes in the Planning Area. We recommend that nursing homes that meet the occupancy threshold, be permitted to add 10 beds or 10% of licensed capacity every two years, and not be tied to the planning area occupancy. This minimal incremental number of beds would support the ability of proven quality nursing homes to maintain access for their local populations, and would also support the ability of these nursing homes to upgrade their physical plants and decrease triple and quad occupancy rooms. Nursing home regulations in Illinois, Maryland, New Jersey and Delaware include similar provisions yet these states have not seen any large increases in licensed nursing home beds given that market and financial feasibility factors inherently limit over-capacity. In addition, we recommend that the occupancy threshold be decreased to 92% for the prior 12 month period, to more accurately reflect the definition of high occupancy for quality nursing homes, including those facilities that have a large volume of short-term admissions and discharges.

- Section 6 / Filing of an Application Pre-Requisites: We recommend that the requirement for outstanding obligations for Quality Assurance Program (QAAP) or Civil Monetary Penalties (CMP) we changed to refer to these obligations that have due dates at least 60 days prior to the application filing so that the applicant is considered current in payment.
- Section 7 / Relocation of Beds: We believe that the restrictions in Section 7 that allow beds to be relocated from a "donor" facility only once every seven years is an arbitrary restriction and not related to any factual evidence that more frequent relocations may be against the public interest. Relocation of beds to facilities seeking additional beds may help to "right size" facilities within the planning area without increasing the total supply of licensed beds. Additionally, the current Standards may actually prop up poor performing nursing homes that have excess licensed beds, thereby resulting in a distribution of beds in the planning area that does not respond to local needs. We recommend that the seven year restriction be deleted from the Bed Relocation Section.

The comparative review criteria can be an excellent public policy tool to encourage providers to develop nursing homes that are progressive and that meet the current and future needs of Michigan citizens. However, we believe that the comparative review criteria in the 2010 Standards do not include criteria that differentiate among applicants and do not encourage providers

to offer outcome driven post-acute services in nursing homes designed with technological innovations. Examples that should be reviewed and considered for revision are as follows:

- Section 10(2): This section favors high Medicaid utilization, and does not recognize the value of innovative nursing homes that focus on providing post-acute care, and therefore provide large Medicare utilization. Especially in light of the current focus by the federal Medicare program to decrease re-hospitalizations, we believe that the points should be revised to not penalize nursing homes that focus on post-acute care, as such nursing homes do not provide a large percentage of long-term care that is typically reimbursed by Medicaid.
- Section 10(15): This section does not go far enough to award points to quality post-acute providers, in recognition of the federal and state initiatives for electronic technology capabilities in nursing homes.
- Decreased re-hospitalization Initiatives: We recommend addition of new comparative review criteria to award points to nursing homes that demonstrate initiatives aimed at decreasing re-hospitalization, in recognition of the federal focus on this issue. The CON comparative review criteria are missing an opportunity to reinforce federally recognized quality indicators.
- Section 10(4) Quality: We recommend increasing the point deduction for poor quality nursing homes to 25 points, to ensure that Michigan residents receive nursing home services at facilities and by providers who have a demonstrated track record of consistent quality nursing home services.
- Section 10(5) Culture Change: The current approved Department Culture Change list is outdated and should be updated to reflect alternative proven Culture Change initiatives such as post-acute, use of innovative technology, successfully discharge outcomes that enable patients to return to the community independently and with sufficient community support and transition to avoid re-hospitalization. The current Department approved Culture Change programs tend to focus on long-term stay residents and not on post-acute admissions. In addition, the worksheet that the Department uses to evaluate Culture Change should be revised to better reflect the criteria.
- Sections 10(6) and 10(11) Financial Strength of Applicant: We recommend increasing points for applicants who provide cash for project funding and audited financial statements as a demonstration of financial strength.

- Section 10 (7): This Section awards five points for sprinkling of the proposed nursing home space to be constructed even though this is already required by Medicare/Medicaid or applicable State Fire Code. Thus, every CON applicant would earn these five points, the criterion has limited value in a comparative review, and is duplicative of current standards. We believe this criterion should be eliminated as it provides no value.

Thank you for this opportunity to comment on the CON Standards for Nursing Home and Hospital Long-Term Care Unit Beds. We urge the Commission to re-open the review of the Nursing Home Standards in order to ensure development of Standards that will better serve the vital needs of Michigan residents seeking quality nursing home services.

Sincerely,

Lisa S. Rosenthal
Director of Health Planning
HCR ManorCare

Submitted October 24, 2012

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 8:49 AM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: CTPublicCommentHFHS102412.pdf

1. Name: Karen Kippen
2. Organization: Henry Ford Health System 3. Phone: 313-874-6985 4. Email: kkippen1@hfhs.org 5. Standards: CT 6. Testimony:

Content-Length: 323864

Corporate Planning
1 Ford Place, 3B
Detroit, MI 48202-3450
(313) 874-5000 Office
(313) 874-4030 Fax

October 23, 2012

James B. Falahee, Jr, J.D.
CoN Commission Chairperson
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Falahee:

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need (CoN) review standards for Computed Tomography (CT) Services.

On January 1, 2011, CMS instituted a new policy bundling the abdomen and pelvis CTs performed in one session to a new single CPT code. The current CON Standards calculate CT equivalents based on "billable" procedures and these Standards were revised without fully understanding the large impact bundling would have on calculating CT equivalents.

As a "fix" for this issue, the current CT standards define "Billable procedure" as a CT procedure billed as a single unit under procedure codes in effect on December 31, 2010, and performed in Michigan. Applying 2010 coding to 2011 data was much more labor intensive but did allow us to report data for CT volumes for 2011 and calculate equivalent volumes that were accurate.

In order to create a more efficient process and a viable long term solution HFHS suggests the following:

- Convene a CT workgroup to look at alternative methods of measuring usage for CTs in the future. Resolutions created may be applicable for other covered services, as bundled payments may impact MRI or PET billing.

We look forward to working with the Commission and the Department to address these concerns and would actively participate in a workgroup.

Respectfully,

Karen E. Kippen

Karen E. Kippen
Henry Ford Health System
Director, Strategic Planning

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 8:49 AM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: CTPublicCommentHFHS102412.pdf

1. Name: Karen Kippen
2. Organization: Henry Ford Health System 3. Phone: 313-874-6985 4. Email: kkippen1@hfhs.org 5. Standards: CT 6. Testimony:

Content-Length: 323864

Corporate Planning
1 Ford Place, 3B
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(313) 874-5000 Office
(313) 874-4030 Fax

October 23, 2012

James B. Falahee, Jr, J.D.
CoN Commission Chairperson
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Falahee:

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need (CoN) review standards for Urinary Extracorporeal Shockwave Lithotripsy (UESWL) Services.

Henry Ford Health System supports the continued regulation of lithotripsy services and offers the following comments:

The current lithotripsy standards work extremely well by encouraging the use of mobile lithotripsy services, which allows many facilities to share equipment. This is especially useful in a relatively low-volume service like lithotripsy. By sharing equipment, and the technologist that operates the equipment, these standards also help to ensure high quality service by maintaining consistent and relatively high volumes performed by the technologist. If the service were deregulated, there would likely be a proliferation of units, which means lower volume per operator and the potential for lower quality.

In other states without CON, physicians have been moving these procedures out of the operating room and into their offices and in some cases, purchasing less powerful units of their own rather than utilizing mobile service. Although lithotripsy is a non-invasive treatment, it does require anesthesia and has the potential for serious complications, therefore performing these procedures in an operating room or at least within a surgical department is a more appropriate setting. Because lithotripsy is not covered by Stark regulations, the CON regulations help to reduce physician self-referral and keep the service in the most appropriate setting.

We appreciate your time in considering our comments and ask that you support the current lithotripsy standards and the continued regulation of this service.

Respectfully,

Karen E Kippen

Karen E. Kippen
Director, Strategic Planning

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 2:19 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: UESWLPublicCommentHFHS102412.pdf

1. Name: Karen Kippen
2. Organization: Henry Ford Health System 3. Phone: 313-874-6985 4. Email: kkippen1@hfhs.org 5. Standards: Litho 6. Testimony:

Content-Length: 355603

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 3:16 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: NICUPublicCommentHFHS102412.pdf

1. Name: Karen Kippen
2. Organization: Henry Ford Health System 3. Phone: 313-874-6985 4. Email: kkippen1@hfhs.org 5. Standards: NICU 6. Testimony:

Content-Length: 300934

Corporate Planning
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October 23, 2012

James B. Falahee, Jr, J.D.
CoN Commission Chairperson
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Falahee:

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need (CoN) review standards for Neonatal Intensive Care Services/Beds (NICU).

Henry Ford Health System supports the continued regulation of NICU services and offers the following comments:

The current NICU standards require for each of the most recent 3 years, 2,000 or more live births, if the licensed site is located in a metropolitan statistical area county; or 600 or more live births, if the licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles (surface travel) from the nearest licensed site that operates or has valid CON approval to operate NICU services.

Recent published literature supports the existence of a NICU if there is a delivery service with greater than 1,500 births per year. Therefore, we are asking for consideration to review and discuss an initiation minimum volume of 1,500 births per year in the most recent 3 years in a metropolitan statistical area county.

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

Respectfully,

Karen E. Kippen
Director, Strategic Planning

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Thursday, October 18, 2012 11:22 AM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)

1. Name: Linda Beushausen
2. Organization: Hospice at Home; Hospice and Palliative Care Association of Michigan 3. Phone: 269-429-7100 4. Email: lbeushausen@hospiceathomecares.org
5. Standards: NH
6. Testimony: Thank you for the opportunity to provide comments regarding the Certificate of Need Review Standards for Nursing Home and Hospital Long-Term Care Unit Beds. I am writing to request consideration of an increase to the number of beds allocated to the Special Pool for Hospice.

This pool was created in recognition that the citizens of Michigan needed greater access to inpatient hospice options. These beds must be utilized only by licensed hospice providers and are used to provide a place for hospice patients to live when they do not have a home of their own to live in or do not have any relatives or friends to provide the support needed for them to stay in their home. These inpatient hospice facilities are designed specifically to enhance end of life care. For example, these facilities have all private rooms with space to accommodate visitors 24/7. Because most counties do not have nursing home beds available in the general inventory, the Commission decided to create a pool of beds that could only be accessed by hospice providers for this purpose and could be accessed from any county in the State.

Beds from the hospice pool are limited to no more than 30 beds per applicant, and no more than 1 applicant per county. This ensures a broad geographic distribution of these beds and helps to increase access to hospice patients across the State. However, there are only 130 beds in the pool currently (all have been granted to CON applicants), resulting in only 9 facilities being able to obtain beds from it. This means that patients in only 9 counties, out of 83, have access to these beds.

Due to federal regulations, Medicaid can only provide room and board reimbursement for hospice patients if they are in a licensed nursing home or hospital bed. Therefore, the only option a Medicaid patient has for inpatient hospice care is a hospital, nursing home, or an inpatient hospice facility that has obtained beds from this pool (or the general nursing home pool) and therefore qualifies for nursing home licensure. Other insurers allow for these services to be provided in hospice residence beds, but as Michigan's Medicaid population has increased significantly over the past 4 years, hospice providers in Michigan have found it difficult to operate without nursing home licensure. A few facilities have been able to obtain beds out of the general inventory for their county, but it is often difficult to find beds available and Medicaid officials have expressed concern over using general inventory beds for this purpose.

For all of the above reasons we request that the CON Commission add 130 beds to the Special Pool for Hospice, doubling the size and the number of counties that could benefit from the pool. If you feel that is too much, we would request at least 60 additional beds. In addition, we would like to recommend that the maximum number of beds allowed by a facility be 20 beds, rather than 30. This will ensure that the additional beds will provide the greatest geographic access, while still allowing each facility enough beds to be financially viable.

Thank you for your consideration.
Linda Beushausen
President and CEO
Hospice at Home
Board Chair, Hospice and Palliative Care Association of Michigan 7. Testimony:

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 4:44 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: MAPCCcommentsonnursinghomestandardsOctober2012.doc

1. Name: Cean Eppelheimer
2. Organization: Michigan Alliance for Person Centered Communities 3. Phone: 517-927-1875 4. Email: ceppelheimer@phinational.org 5. Standards: NH 6. Testimony:

Content-Length: 102355

October 24, 2012

CON Commission
Michigan Department of Community Health
Lansing, MI 48909

RE: Nursing Home and Hospital Long-Term Care Unit Standards

Dear Commission Members,

Thank you for the opportunity to comment on the Nursing Homes and Hospital Long-Term Care Unit Standards. By way of introduction, the Michigan Alliance for Person-Centered Communities (MAPCC) is a diverse coalition of organizations affiliated with the full array of community and residential Michigan's long-term supports and services. We come together to promote the creation of service communities deeply rooted in the dignity and respect for people receiving supports and services and those who deliver those services. We believe that long-term supports and services should be grounded in relationships and opportunities for self-determination and personal growth for all. MAPCC is the place for "culture change" advocates to work together.

The purpose of our comments are to support the retention of the of the culture change provisions within the competitive review sections of the Nursing Home and Hospital Long-Term Care Unit standards. We believe that a nursing home or entire company actively engaged in culture change is a home committed to quality improvement and focused on serving residents, their families, and empowering staff.

There is a growing body of evidence to support the assertion that person centered culture change initiatives, when implemented thoughtfully, lead to concrete benefits for nursing home residents—including improvements to both quality of life and clinical outcomes. In addition, person-centered culture change has well-documented benefits for residents' family members and nursing home staff which in turn, impact and benefit the resident.

In 2006, the Colorado Foundation for Medical Care (CFMC) conducted a literature review on the evidence based support for culture change, under contract from the Centers for Medicare and Medicaid Services. CFMC's approach was to identify 25 specific resident-centered/directed culture change practices, and determine whether reliable research connected these to positive outcomes for residents and staff. Significantly, the review

found "documented evidence" that 20 out of the 25 practices led to positive outcomes in one or more of the following areas: *pressure ulcers*, *physical restraints*, *depression*, *pain*, *incontinence*, *rate of transfer to acute care*, *medication safety*, and *staff turnover*. CFMC did not rule out the possibility that the remaining five practices might have positive impacts as well.[1]

In addition, extensive research has been conducted on The Green House ® care model, which is grounded in person-centered principles of culture change.[2] One two-year study compared the experiences of Green House residents to those living in more traditionally structured control facilities. The study found that the Green House residents had stronger quality of care indicators; for example, they maintained self-care abilities for a longer period of time, and experienced less depression. In terms of quality of life, the Green House residents reported notably greater satisfaction in a number of key areas— including *meaningful activity*, *individuality*, *privacy*, *dignity*, *relationships*, *food enjoyment*, and *autonomy*.[3] Further research indicated that family members of residents responded more positively to The Green House model than to traditional nursing home sites; specifically, family members indicated higher degrees of satisfaction in the areas of *health care*, *autonomy*, *physical environment*, and *general amenities*.[4]

Other studies have measured the impact of The Eden Alternative®, a nonprofit organization dedicated to "transforming care environments into habitats for human beings that promote quality of life for all involved," as well as "guiding organizations through the journey of culture change."[5] Significantly, a two-year study of a nursing facility that implemented The Eden Alternative approach found improvements in terms of family member satisfaction and residents' levels of depression.[6] More recently, the U.K.-based Accord Housing Association reported that implementing the Eden Alternative approach to supporting people with dementia led to a dramatic drop in the number of residents at a care facility who were prescribed psychotropic drugs; pre-implementation, 21 residents were prescribed the drugs, while post-implementation the number dropped to just one.[7]

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[1] Colorado Foundation for Medical Care. (August 7, 2006). *Measuring Culture Change: Literature Review.* Publication No. PM-411-114 CO 2006. Denver, CO: CFMC. Available online at: http://www.cfmc.org/files/nh/MCC%20Lit%20Review.pdf

[2] According to The Green House website, their model consists of: "a de-institutionalization effort designed to restore individuals to a home in the community by combining small homes with the full range of personal care and clinical services expected in high-quality nursing homes." For more information, please see: http://thegreenhouseproject.org/about-us/mission-vision/

[3] Kane, R. A., Lum, T. Y., Cutler, L. J., Degenholtz, H. B., & Yu, T. C. (2007). Resident outcomes in small-house nursing homes: A longitudinal evaluation of the initial Green House program. *Journal of the American Geriatrics Society, 55*(6), 832-839.

[4] Lum, T., Kane, R., & Cutler, L. (2009). Effects of Green House® nursing homes on residents' families. *Healthcare Financing Review, 30,* 35-51.

[5] For more information, see http://www.edenalt.org/

[6] Robinson, S. B., & Rosher, R. B. (2006). Tangling with the barriers to culture change: Creating a resident-centered nursing home environment. *Journal of Gerontological Nursing, 32*(10), 19-25. See also Rosher, R. B., & Robinson, S. (2005). Impact of the Eden Alternative on family satisfaction. *Journal of the American Medical Directors Association, 6*(3), 189-193.

[7] The Accord Group reported these results online at: http://accordha.org.uk/articles/20-Housing-Association-sees-dramatic-fall-in-use-of-psychotropic-drugs-thanks-to-the-Eden-Alternative-

Culture change models have also produced documented workforce and organizational benefits. For example, a study of the Wellspring Model for Improving Nursing Home Quality found that implementation of the model led to: declines (or slower increases) in rates of staff turnover; improved performances on annual inspections by the state; improved staff-resident interaction; and generally lower costs than those incurred by comparison facilities.[8] Workforce and organizational benefits such as decreased staff turnover extend to the resident as they enjoy more consistent relationships and predictability.

In response to this growing evidence base, government agencies have increasingly supported person-centered culture change initiatives. As one example, in 2008, the Centers for Medicare and Medicaid Services co-sponsored "Creating Home in the Nursing Home," a national symposium to generate discussion and improved coordination around environmental culture change efforts. CMS subsequently revised sections of the Interpretive Guidelines for evaluating quality of life in nursing homes. As noted by Amy Elliot, Policy Analyst for the Pioneer Network: "*The new guidelines support culture change transformations through enhanced instructions to surveyors on how to evaluate compliance with regulations, including resident choices about daily schedules (e.g., when to get up, go to bed, eat, bathe), visitation issues, homelike environment, food procurement, and expand significantly on guidance related to lighting.*"[9]

CMS has since demonstrated continued interest in supporting person-centered culture change work. In May 2010, the Pioneer Network and CMS co-sponsored an online symposium focused on dining initiatives that promote culture change in nursing homes, which explored the potential and perceived regulatory barriers to making such transformations. The symposium addressed a wide range of dining issues, and resulted in new practice standards that reflect a more person-centered approach.[10]

MAPCC believes that CON preference should be given to homes and companies that have embraced culture change and person-centered services. Please do not hesitate to contact me for additional information on this topic.

Sincerely,

Cean Eppelheimer
Co-Facilitator

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[8] Stone, R., Reinhard, S., Bowers, B., Zimmerman, D., Phillips, C., Hawes, C., et al. (August, 2002). *Evaluation of the wellspring model for improving nursing home quality,* No. 550. New York: Commonwealth Fund.

[9] A. E. Elliot, "Occupancy and Revenue Gains from Culture Change in Nursing Homes: A Win-Win Innovation for a New Age of Long-Term Care," *Seniors Housing & Care Journal*, 2010 18(1):61–76.

[10] For background information on this symposium, please see: http://www.pioneernetwork.net/Data/Documents/dining%20symposium%20background%20paper%201-28-10.pdf

October 24, 2012

CON Commission
Michigan Department of Community Health
Lansing, MI 48909

RE: Nursing Home and Hospital Long-Term Care Unit Standards

Dear Commission Members,

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found "documented evidence" that 20 out of the 25 practices led to positive outcomes in one or more of the following areas: *pressure ulcers*, *physical restraints*, *depression*, *pain*, *incontinence*, *rate of transfer to acute care*, *medication safety*, and *staff turnover*. CFMC did not rule out the possibility that the remaining five practices might have positive impacts as well.[1]

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[1] Colorado Foundation for Medical Care. (August 7, 2006). *Measuring Culture Change: Literature Review.* Publication No. PM-411-114 CO 2006. Denver, CO: CFMC. Available online at: http://www.cfmc.org/files/nh/MCC%20Lit%20Review.pdf

[2] According to The Green House website, their model consists of: "a de-institutionalization effort designed to restore individuals to a home in the community by combining small homes with the full range of personal care and clinical services expected in high-quality nursing homes." For more information, please see: http://thegreenhouseproject.org/about-us/mission-vision/

[3] Kane, R. A., Lum, T. Y., Cutler, L. J., Degenholtz, H. B., & Yu, T. C. (2007). Resident outcomes in small-house nursing homes: A longitudinal evaluation of the initial Green House program. *Journal of the American Geriatrics Society, 55*(6), 832-839.

[4] Lum, T., Kane, R., & Cutler, L. (2009). Effects of Green House® nursing homes on residents' families. *Healthcare Financing Review, 30,* 35-51.

[5] For more information, see http://www.edenalt.org/

[6] Robinson, S. B., & Rosher, R. B. (2006). Tangling with the barriers to culture change: Creating a resident-centered nursing home environment. *Journal of Gerontological Nursing, 32*(10), 19-25. See also Rosher, R. B., & Robinson, S. (2005). Impact of the Eden Alternative on family satisfaction. *Journal of the American Medical Directors Association, 6*(3), 189-193.

[7] The Accord Group reported these results online at: http://accordha.org.uk/articles/20-Housing-Association-sees-dramatic-fall-in-use-of-psychotropic-drugs-thanks-to-the-Eden-Alternative-

Culture change models have also produced documented workforce and organizational benefits. For example, a study of the Wellspring Model for Improving Nursing Home Quality found that implementation of the model led to: declines (or slower increases) in rates of staff turnover; improved performances on annual inspections by the state; improved staff-resident interaction; and generally lower costs than those incurred by comparison facilities.[8] Workforce and organizational benefits such as decreased staff turnover extend to the resident as they enjoy more consistent relationships and predictability.

In response to this growing evidence base, government agencies have increasingly supported person-centered culture change initiatives. As one example, in 2008, the Centers for Medicare and Medicaid Services co-sponsored "Creating Home in the Nursing Home," a national symposium to generate discussion and improved coordination around environmental culture change efforts. CMS subsequently revised sections of the Interpretive Guidelines for evaluating quality of life in nursing homes. As noted by Amy Elliot, Policy Analyst for the Pioneer Network: "*The new guidelines support culture change transformations through enhanced instructions to surveyors on how to evaluate compliance with regulations, including resident choices about daily schedules (e.g., when to get up, go to bed, eat, bathe), visitation issues, homelike environment, food procurement, and expand significantly on guidance related to lighting.*"[9]

CMS has since demonstrated continued interest in supporting person-centered culture change work. In May 2010, the Pioneer Network and CMS co-sponsored an online symposium focused on dining initiatives that promote culture change in nursing homes, which explored the potential and perceived regulatory barriers to making such transformations. The symposium addressed a wide range of dining issues, and resulted in new practice standards that reflect a more person-centered approach.[10]

MAPCC believes that CON preference should be given to homes and companies that have embraced culture change and person-centered services. Please do not hesitate to contact me for additional information on this topic.

Sincerely,

Cean Eppelheimer
Co-Facilitator

---

[8] Stone, R., Reinhard, S., Bowers, B., Zimmerman, D., Phillips, C., Hawes, C., et al. (August, 2002). *Evaluation of the wellspring model for improving nursing home quality,* No. 550. New York: Commonwealth Fund.

[9] A. E. Elliot, "Occupancy and Revenue Gains from Culture Change in Nursing Homes: A Win-Win Innovation for a New Age of Long-Term Care," *Seniors Housing & Care Journal*, 2010 18(1):61–76.

[10] For background information on this symposium, please see: http://www.pioneernetwork.net/Data/Documents/dining%20symposium%20background%20paper%201-28-10.pdf

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 8:49 AM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: CON-PublicComent-NICU-Standards-10-11-12-FINAL.pdf

1. Name: Rose Mary Asman, R.N., M.P.A.
2. Organization: MDCH - DFCH
3. Phone: 517-335-8055
4. Email: AsmanR@michigan.gov
5. Standards: NICU
6. Testimony: See Attached pdf document

Content-Length: 65731

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 8:49 AM
To: MDCH-ConWebTeam
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1. Name: Rose Mary Asman, R.N., M.P.A.
2. Organization: MDCH - DFCH
3. Phone: 517-335-8055
4. Email: AsmanR@michigan.gov
5. Standards: NICU
6. Testimony: See Attached pdf document

Content-Length: 65731

Written Comment for October 10, 2012 – October 24, 2012 public Comment Period
Neonatal Intensive Care Services Beds (NICU) Standards

The Division of Family and Community Health (DFCH) is responsible for the implementation of perinatal regionalization in the state. In April 2009, *Perinatal Regionalization: Implications for Michigan* was presented to the legislature. This document was created by perinatal experts and stakeholders from across the state. The document outlines the Michigan Perinatal Levels of Care in the state.

DFCH is recommending changes in the Certificate of Need NICU standards based on the levels of care guidelines.

The Michigan Perinatal Level of Care Guidelines are based on American Academy of Pediatrics [AAP]/American Congress of Obstetricians and Gynecologists [ACOG] Level of Care Guidelines modified to reflect Michigan's standards. The report *Perinatal Regionalization: Implications for Michigan* (2009)[1.] outlines three levels of care for birth hospitals in Michigan. The current levels of care for newborns include Level I (basic nursery), Level II (special care nursery) and Level III (NICU). See Appendix A for a brief overview of the Level of Care criteria.

Currently in Michigan, the only level of care that has regulation is Level III (NICU) through the CON NICU Bed Standards. There are 20 NICUs in the state that have a CON for NICU beds. Port Huron Hospital has a CON for 4 NICU beds, however they do not consider their unit a NICU, and they do not have a neonatologist on staff.

There is NO regulation regarding Level II hospitals or Special Care Nursery beds in the state. There is wide variation in the level of care provided in Level II units. Some will only care for infants greater than 35 weeks gestation (which is the same as a Level I hospital), while other units push the limits with the length of time babies are on ventilators.

Among the NICUs in the state, there are three models of bed use. The first model is that the NICU has the exact same number of NICU beds as CON beds and they do not have any special care unit. The second model is that the unit has more NICU beds on the unit than they have licensed by CON. The unlicensed beds or bassinettes are within the same unit as the licensed beds for the NICU. These beds are used when an infant has less acuity than a NICU infant. Thus, 50% of the NICUs in the state have "unlicensed beds" in the same unit as the NICU. The third model found in the state is that the number of NICU beds and the number of licensed CON NICU beds are the same. In addition, the hospital has a special care unit that is in a separate space from the NICU unit.

Nationally, the Level of Care Guidelines have changed and the Michigan Perinatal Level of Care Guidelines will need to be updated. The AAP[2] recommends FOUR levels of care in its policy released on August 27, 2012. Level I remains unchanged. Level II are the special care nursery beds. Level III and Level IV are NICU beds.

Authoritative recognition is needed to enforce the recommendations for Levels of Care in Michigan. The national levels of care, which separate Level III and Level IV NICUs needs to be addressed in NICU Bed Standards. An Addendum for the NICU standards seems logical for Level II special care nursery beds.

The Michigan Perinatal Guidelines recommend that if the authoritative recognition of levels of care is through the Certificate of Need process, create a provision to retrospectively change a hospital's perinatal level of care designation. Hospitals cannot and should not be grandfathered into an "old system."

Literature and evidence indicate that states with a regionalized and coordinated perinatal system of care better assure that pregnant women and babies are more likely to deliver in an appropriate hospital setting and receive appropriate services to meet their needs. A statewide mechanism to oversee and enforce adherence to the Michigan guidelines is needed to ensure that hospitals and NICUs care for only those mothers and neonates for which they are qualified. The process of regulation of level of care nursery beds is needed to assure quality, consistency, safety, education, structure, data and cost containment in the state.

Five workgroups were established during FY 12 to develop a statewide perinatal coordinated system. One workgroup was charged with creating a process for designation, verification and certification of birth hospitals in Michigan. The workgroup recommended that all hospitals will apply for their desired designation. If the level desired is regulated by CON, the hospital must meet all the requirements in their Standards. The workgroup made recommendations for specific application, application acceptance, site verification process, peer review teams, denial, appeal, and corrective action. Key in the workgroups recommendations is to have Certificate of Need involved in the process of designation Levels of Care among birth hospitals.

In summary, the state needs to regulate not only NICU nursery beds, but also Level II or special care nursery beds. Additionally, the Certificate of Need process needs to change the rules regarding grandfathering in hospitals under the "old" rules.

Thank you for your consideration.

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

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

Appendix A

Brief Overview of Perinatal Level of Care Guidelines

Basic Level

- *Level I (Basic)*
  - *Community-Based Maternal-Newborn Service*
  - *≥ 35 weeks gestation*
  - *Care if uncomplicated births*

Special Care Nursery – There is NO REGULATION for THESE BEDS

- *Level II A (Subspecialty)*
  - *Community-Based Maternal-Newborn Service with a Special Care Nursery*
  - *> 32 weeks gestation*
  - *> 1,500 gm*
  - *Uncomplicated preterm infant with problems that are expected to resolve rapidly*
  - *Stabilization of sick newborn infants until transfer only*
  - *No surgery*

- *Level II B (Subspecialty)*
  - *Community-Based Maternal-Newborn Service with a Special Care Nursery*
  - *> 32 weeks gestation*
  - *> 1,500 gm*
  - *Uncomplicated preterm infant*
  - *CPAP and mechanical ventilation for less than 24 hours*
  - *No surgery*

NICU Beds – All 3 of these levels follow the CON NICU Bed Schedule

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

- *Level III C (Subspecialty)*
  - *Perinatal Care Center or Freestanding Pediatric Hospital with Neonatal Subspecialty Service*
  - *< 28 weeks gestation and weight < 1,000 gms or with complex illnesses*
  - *At least 70 VLBW infants per year*
  - *Infants with ECMO or open cardiac surgery*
  - *All maternal conditions*

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Tuesday, October 23, 2012 10:03 AM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)

1. Name: Amy Barkholz
2. Organization: Michigan Health & Hospital Association 3. Phone: 571-323-3443 4. Email: abarkholz@mha.org 5. Standards: NH 6. Testimony: The Michigan Health & Hospital Association supports the recommendations the Hospice and Palliative Care Association of Michigan submitted in their Oct. 17 letter to the Commission. The letter requested an additional 130 beds to the Special Pool for Hospice, doubling the size and the number of counties that could benefit from the pool. In addition, They recommended that the maximum number of beds allowed by a facility be 20 beds, rather than 30 to help ensure that the additional beds will provide the greatest geographic access, while still allowing each facility enough beds to be financially viable.
7. Testimony:

Date: 10/24/2012

To: Certificate of Need Commission

From: Sarah Slocum, State Long Term Care Ombudsman

Re: Comments on NH/HLTCU CON standards

I am submitting comments for consideration in the review of the Nursing Home/Hospital Long Term Care Unit CON standards. The Long Term Care Ombudsman (LTCO) Program is charged with providing a voice to the concerns, wishes and needs of residents of licensed LTC facilities. In that role, I present the following brief comments as areas of exploration by the NH Standard Advisory Committee, should one be appointed by the CON Commission.

Changes to the current NH/HLTCU CON Standards:

1. Include MI Choice need and supply in calculations of regional or county LTC needs, not just NH beds. The MI Choice Home and Community Based Waiver program serves people who meet the NH level of care, but provides the services in non-facility settings. Including the MI Choice program capacity in the calculation of "NH Bed-Need" would create a more realistic picture of all the NH level of care services available, or needed, in a community.

2. Deduct points from applicants who have failed to meet the requirements/commitments made in the most recent previous CON application. Owners who do not complete previously agreed to CON requirements should not be granted any new CONs until the requirements are met.

3. In the Comparative Review section, grant additional points for proposals including 100% dual Medicare/Medicaid certification in the proposed project.

4. Also in the Comparative Review section, specify state-approved Quality Improvement projects that show participation of that applicant in meaningful and continuing Quality Improvement efforts. For example, participation for multiple years in the Advancing Excellence project, if it results in quality improvements – such as reduced pressure sore rate, reduced use of

restraints, and complete adoption of consistent assignment of direct care staff – should be rewarded with additional points.

5. On page 15, item (5), I urge you to retain this section granting extra points for meaningful participation in a culture change model approved by the state.

6. In the Comparative Review section, on page 15, item (7) should be deleted. All Medicare/Medicaid certified NHs will be required to be fully sprinklered by 2013. No extra points should be awarded for meeting a minimum requirement.

7. On page 15, item (10), reduce the number of beds from 150 to 80. Smaller facilities have been found to be beneficial and usually better able to provide person-centered care than larger facilities.

8. On page 16, item (15) increase the points awarded for wireless nursing call systems, wireless internet in facility, and computer stations/internet cafes for residents from 1 point each to 5 points each.

Thank you for the opportunity to provide input on the NH/HLTCU standards. Many improvements were made to these standards during the last NHSAC deliberations. I request that the Department and Commissioners consider appointing a representative from the Michigan LTC Ombudsman Program to the next NHSAC to represent the voice of residents in the process.

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 4:49 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: CON_2012_first_testimony.doc

1. Name: Sarah Slocum
2. Organization: Michigan Long Term Care Ombudsman Program 3. Phone: 517/335-0148 4. Email: slocums@michigan.gov 5. Standards: NH 6. Testimony:

Content-Length: 34613

Date: 10/24/2012

To: Certificate of Need Commission

From: Sarah Slocum, State Long Term Care Ombudsman

Re: Comments on NH/HLTCU CON standards

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Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 2:36 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)

1. Name: Monica Harrison
2. Organization: Oakwood Healthcare, Inc.
3. Phone: 313-586-5478
4. Email: monica.harrison@oakwood.org
5. Standards: CT
6. Testimony: October 24, 2012

Mr. James Falahee, Chair
Certificate of Need Commission

Dear Mr. Falahee:

Oakwood Healthcare would like to thank the Commission for this opportunity to provide comments on the CON Review Standards for Computed Tomography (CT) Scanner Services. These standards became effective on February 27, 2012.

A few years ago there were some changes in CMS billing definitions, most notably the abdomen and pelvis. These changes resulted in the abdomen and pelvis being billed together as one scan rather than two which was previously the case. To offset these changes, the CT Review Standards were modified with a revision to the definition of a CT billable procedure. This definition reads "a CT procedure billed as a single unit under procedure codes in effect on December 31, 2010 and performed in Michigan." Thus, currently a facility must count CT equivalents in separate ways: one, to meet billing requirements and two, to comply with CON and annual survey requirements. Other CON standards more clearly delineate how procedures are counted. Therefore, it may prove beneficial to better define "CT procedure" outside of billing parameters.

We feel that these items could be adequately addressed in a workgroup setting; and we would be happy to work with the Department and Commission in this regard.

Again, thank you for the opportunity to express our views and concerns.

Monica Harrison
Sr. Planning Analyst
Oakwood Healthcare, Inc.
313-586-5478

7. Testimony:

HOSPICE & PALLIATIVE CARE
ASSOCIATION OF MICHIGAN

October 17, 2012

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

Re: CON Standards for Nursing Home and HLTCU Beds

Dear Chairman Falahee,

Thank you for the opportunity to provide comments regarding the Certificate of Need Review Standards for Nursing Home and Hospital Long-Term Care Unit Beds. I am writing to request consideration of an increase to the number of beds allocated to the Special Pool for Hospice.

This pool was created in recognition that the citizens of Michigan needed greater access to inpatient hospice options. These beds must be utilized only by licensed hospice providers and are used to provide a place for hospice patients to live when they do not have a home of their own to live in or do not have any relatives or friends to provide the support needed for them to stay in their home. These inpatient hospice facilities are designed specifically to enhance end of life care. For example, these facilities have all private rooms with space to accommodate visitors 24/7. Because most counties do not have nursing home beds available in the general inventory, the Commission decided to create a pool of beds that could only be accessed by hospice providers for this purpose and could be accessed from any county in the State.

Beds from the hospice pool are limited to no more than 30 beds per applicant, and no more than 1 applicant per county. This ensures a broad geographic distribution of these beds and helps to increase access to hospice patients across the State. However, there are only 130 beds in the pool currently (all have been granted to CON applicants), resulting in only 9 facilities being able to obtain beds from it. This means that patients in only 9 counties, out of 83, have access to these beds.

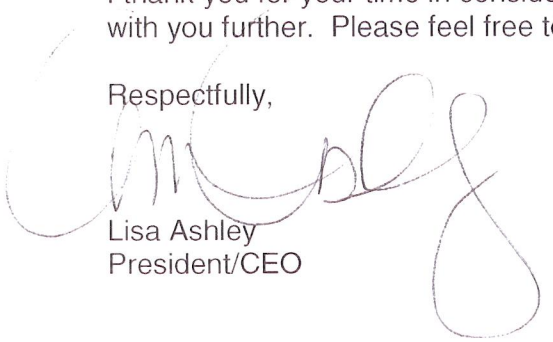
Due to federal regulations, Medicaid can only provide room and board reimbursement for hospice patients if they are in a licensed nursing home or hospital bed. Therefore, the only option a Medicaid patient has for inpatient hospice care is a hospital, nursing home, or an inpatient hospice facility that has obtained beds from this pool (or the general nursing home pool) and therefore qualifies for nursing home licensure. Other insurers allow for these services to be provided in hospice residence beds, but as Michigan's Medicaid population has increased significantly over the past 4 years, hospice providers in Michigan have found it difficult to operate without nursing home licensure. A few facilities have been able to obtain beds out of the general inventory for their county, but it is often difficult to find beds

available and Medicaid officials have expressed concern over using general inventory beds for this purpose.

For all of the above reasons we request that the CON Commission add 130 beds to the Special Pool for Hospice, doubling the size and the number of counties that could benefit from the pool. If you feel that is too much, we would request at least 60 additional beds. In addition, we would like to recommend that the maximum number of beds allowed by a facility be 20 beds, rather than 30. This will ensure that the additional beds will provide the greatest geographic access, while still allowing each facility enough beds to be financially viable.

I thank you for your time in considering these suggestions and would be happy to discuss these issues with you further. Please feel free to call me at 231-330-4787.

Respectfully,



Lisa Ashley
President/CEO

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 17, 2012 5:01 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: HPCAM__SIGNED_LETTER_10-17-12.pdf

1. Name: Lisa Ashley
2. Organization: Hospice & Palliative Care Association of Michigan 3. Phone: 5176683696 4. Email: LAshley@mihospice.org 5. Standards: NH 6. Testimony:

Content-Length: 1535506

Notice of Public Comment Period

The Michigan Department of Community Health (MDCH) will hold a public comment period for Certificate of Need (CON) Review Standards.

Date: Wednesday, October 10, 2012 - Wednesday, October 24, 2012

■ ■ ■

Air Ambulance Services

Computed Tomography (CT) Scanner Services

Neonatal Intensive Care Services/Beds (NICU)

Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups

Urinary Extracorporeal Shock Wave Lithotripsy Services/ Units

■ ■ ■

The CON Review Standards for Air Ambulance Services, CT Scanner Services, NICU Services/Beds, Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups, and Urinary Extracorporeal Shock Wave Lithotripsy Services/Units are scheduled for review in 2013. The public comment period is to receive testimony on what, if any, changes need to be made and on the need for continued regulation or de-regulation of each of the mentioned standards.

■ ■ ■

Comments may be submitted starting Wednesday, October 10, 2012, in writing via online submission at http://www.michigan.gov/mdch/0,4612,7-132-2945_5106_5409_29279-147062--,00.html and will end no later than 5:00 p.m., Wednesday, October 24, 2012. If you have any questions or concerns, please contact Tania Rodriguez at 517-335-6708.

10/9/12

Notice of Public Comment Period

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Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Tuesday, October 23, 2012 2:06 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: Air_Ambulance_10-2012__001.pdf

1. Name: Meg Tipton
2. Organization: Spectrum Health
3. Phone: 616-391-2043
4. Email: meg.tipton@spectrumhealth.org 5. Standards: AA 6. Testimony:

Content-Length: 38855

SPECTRUM HEALTH

Spectrum Health Butterworth Hospital
100 Michigan Street NE
Grand Rapids, MI 49503-2560
616.391.1774 fax 616.391.2745
spectrum-health.org

October 23, 2012

James B. Falahee, Chair
Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Commissioner Falahee,

This letter is written as formal testimony and support for continued regulation of the CON Review Standards for Air Ambulance Services which went into effect August 12, 2010. It is the position of Spectrum Health that the Air Ambulance Services Standards not be opened for review and further recommends that no changes be made to the CON Standards for Air Ambulance Services at this time.

Spectrum Health appreciates the opportunity to comment on these Standards.

Sincerely,

Robert A. Meeker

Strategic Program Manager

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Tuesday, October 23, 2012 2:06 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: Air_Ambulance_10-2012__001.pdf

1. Name: Meg Tipton
2. Organization: Spectrum Health
3. Phone: 616-391-2043
4. Email: meg.tipton@spectrumhealth.org 5. Standards: AA 6. Testimony:

Content-Length: 38855

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Tuesday, October 23, 2012 2:04 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: CT__scanners__10-2012_001.pdf

1. Name: Meg Tipton
2. Organization: Spectrum Health
3. Phone: 616-391-2043
4. Email: meg.tipton@spectrumhealth.org 5. Standards: CT 6. Testimony:

Content-Length: 40466

SPECTRUM HEALTH

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October 23, 2012

James Falahee, Chair
Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Commissioner Falahee,

This letter is written as formal testimony regarding the CON Review Standards for Computed Tomography (CT) Scanner Services which went into effect February 27, 2012. Spectrum Health appreciates the opportunity to comment on these Standards.

The CT Standards have only recently gone into effect and therefore it is too soon to assess how well they are working. However, we would like to propose that the definition of a CT procedure be addressed. The current definition for a "Billable Procedure" is a CT procedure billed as a *single unit* under procedure codes in effect on December 31, 2010 and performed in Michigan. This definition was proposed as a temporary 'fix' to address a change in CMS billing definitions and has resulted in a requirement that an organization count CT equivalents in two ways: one to satisfy CON requirements and a second to meet billing requirements. We propose that the definition for a CT procedure be independent of any billing considerations. By defining a CT procedure independently it would follow the manner in which other CON standards define the counting of procedures and allow for the actual portrayal of CT equivalents (and therefore volumes) for each CT scanner at an organization.

Spectrum Health appreciates the opportunity to comment on the CON Review Standards for CT, and we will be pleased to participate in this process as appropriate.

Sincerely,

Robert A. Meeker
Strategic Program Manager

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Tuesday, October 23, 2012 2:04 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: CT__scanners__10-2012_001.pdf

1. Name: Meg Tipton
2. Organization: Spectrum Health
3. Phone: 616-391-2043
4. Email: meg.tipton@spectrumhealth.org 5. Standards: CT 6. Testimony:

Content-Length: 40466

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 11:02 AM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: SHtestimony102412.pdf

1. Name: Robert Meeker
2. Organization: Spectrum Health
3. Phone: 616 391-2779
4. Email: robert.meeker@spectrumhealth.org 5. Standards: Litho 6. Testimony:

Content-Length: 44232

SPECTRUM HEALTH

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October 24, 2012

James B. Falahee, Jr., Chair
Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building,
201 Townsend Street
Lansing, Michigan 48913

Dear Mr. Falahee,

Spectrum Health supports continued CON regulation of urinary extracorporeal shock wave lithotripsy (UESWL) services. However, we strongly urge that the CON Commission consider reducing the volume requirement for expanding the number of lithotripsy machines on a given mobile route. The current level of 1800 procedures per machine per year is unrealistically high and inhibits the ability of mobile lithotripsy providers to adequately serve the needs of patients. Without sufficient lithotripsy access, patients with kidney stones may be forced to undergo invasive ureteroscopy procedures, which are inherently more risky and more costly than noninvasive UESWL procedures.

Thank you for the opportunity to comment on this matter which will come before the Commission in 2013. Spectrum Health is willing to participate in the process of revising the CON Standards to make them more responsive to the needs of Michigan patients.

Sincerely,

Robert A. Meeker
Strategic Program Manager

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Tuesday, October 23, 2012 2:07 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: NICU_10-2012.pdf

1. Name: Meg Tipton
2. Organization: Spectrum Health
3. Phone: 616-391-2043
4. Email: meg.tipton@spectrumhealth.org 5. Standards: NICU 6. Testimony:

Content-Length: 36795

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 4:45 PM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)

1. Name: Sean Gehle
2. Organization: St. John Providence Health system 3. Phone: 517-482-1422 4. Email: sean.gehle@stjohn.org 5. Standards: CT 6. Testimony: St. John Providence Health system supports continued regulation of CT services and recommends the following changes to the CT Standards:

Increase volume requirements to initiate a CT service.

Revise language in section 13 to include hospital-based portable CT scanners as a permanent part of initiation, expansion, replacement and acquisition. Delete references to pilot; retain existing requirements 1-5; revise language in the 6th criteria enabling applicant to utilize CT procedures performed to demonstrate need or satisfy CT CON Review standard requirements. Finally, add a requirement to the standards that a portable CT scanner should be paired with or assigned to an existing fixed scanner CON.
7. Testimony:

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 10:05 AM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: UMHS_CT_Public_Comments_23Oct2012.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: 912620

University of Michigan
Hospitals and Health Centers

Steven E. Szelag
Strategic Planner

Operations and Support Services
300 N. Ingalls, 4A11-3
Ann Arbor, MI 48109-5428
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(734) 647-0547 fax
sszelag@med.umich.edu

October 23, 2012

James B. Falahee, J.D. - CoN Commission Chairperson
Certificate of Need Policy
Capitol View Building
201 Townsend Street
Lansing, MI 48913

RE: Computed Tomography – CoN Standards Tri-Annual Review

Dear Commissioner Falahee:

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) supports the overall regulations for this service; however, there are two points that should be addressed:

1. Definition of a CT scanner – The existing definition currently exempts CT scanners used in conjunction with several select modalities from volume driven methodologies. The definition does not exempt CT scanners used in conjunction with Angiography or Interventional Radiology equipment. It is UMHS's position that CT scanners, when used in a subsidiary capacity, with any therapeutic and/or diagnostic modality should be exempted from volume driven methodologies. These technologies are evolving into what is termed "hybrid imaging" – the combination of more than one modality into a single machine.

2. Fixed CT scanners used exclusively for research – To be consistent with other CoN Standards such as MRI and PET; regulations should be developed allowing providers the opportunity to acquire a research CT scanner. This would significantly increase one's ability to evaluate new treatment methods, including drugs, by increasing the speed and reducing the cost for such clinical trials. There is an anticipated need for CT scanners which will be used for research involving human subjects.

These items could be appropriately addressed with an informal Workgroup rather than a Standards Advisory Committee. Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Sincerely,

Steven E. Szelag
Strategic Planner

Corporate Planning
1 Ford Place, 3B
Detroit, MI 48202-3450
(313) 874-5000 Office
(313) 874-4030 Fax

October 23, 2012

James B. Falahee, Jr, J.D.
CoN Commission Chairperson
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Falahee:

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need (CoN) review standards for Urinary Extracorporeal Shockwave Lithotripsy (UESWL) Services.

Henry Ford Health System supports the continued regulation of lithotripsy services and offers the following comments:

The current lithotripsy standards work extremely well by encouraging the use of mobile lithotripsy services, which allows many facilities to share equipment. This is especially useful in a relatively low-volume service like lithotripsy. By sharing equipment, and the technologist that operates the equipment, these standards also help to ensure high quality service by maintaining consistent and relatively high volumes performed by the technologist. If the service were deregulated, there would likely be a proliferation of units, which means lower volume per operator and the potential for lower quality.

In other states without CON, physicians have been moving these procedures out of the operating room and into their offices and in some cases, purchasing less powerful units of their own rather than utilizing mobile service. Although lithotripsy is a non-invasive treatment, it does require anesthesia and has the potential for serious complications, therefore performing these procedures in an operating room or at least within a surgical department is a more appropriate setting. Because lithotripsy is not covered by Stark regulations, the CON regulations help to reduce physician self-referral and keep the service in the most appropriate setting.

We appreciate your time in considering our comments and ask that you support the current lithotripsy standards and the continued regulation of this service.

Respectfully,

Karen E Kippen

Karen E. Kippen
Director, Strategic Planning

UMS
UNITED MEDICAL SYSTEMS

October 17, 2012

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

Re: CON Standards for UESWL Services

Dear Chairman Falahee,

Thank you for the opportunity to provide comments regarding the Certificate of Need Standards for Urinary Extracorporeal Shock Wave Lithotripsy Services. 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. I am writing to encourage the continued regulation of UESWL services and to provide you with support for doing so.

First let me start by explaining my expertise in this area. I am the Chief Executive Officer of United Medical Systems (DE), Inc. (UMS), minority owner of Great Lakes Lithotripsy. UMS provides mobile UESWL (aka lithotripsy) across the United States. In Michigan, UMS owns and manages four mobile lithotripsy routes through several subsidiaries. UMS has been providing transportable lithotripsy services in the United States since 1998 and in Michigan since 2001.

Lithotripsy is a great example of how Certificate of Need in Michigan helps to ensure broad access to high quality healthcare services while keeping costs down. CON has encouraged lithotripsy to become a mobile service in Michigan by requiring multiple inpatient facilities to collaborate and commit MIDB data to the initiation of a new service. Because lithotripsy is not a high volume procedure at any one individual location, it is ideally suited for mobile service which has led to a more efficient and effective means of providing this service to Michigan patients. Rather than each hospital purchasing this expensive piece of equipment and only utilizing it a few days a month, they can instead obtain the services from a mobile service provider and share the costs with all of the other facilities receiving service on that route. This has resulted in an expansion from 4 fixed lithotripsy sites originally to 76 lithotripsy host sites in 2011. These sites range from large tertiary hospitals to small rural critical access hospitals, to freestanding surgery centers. The small rural facilities would never have enough volume to justify a fixed lithotripter, but because of the CON system here in Michigan, now can provide this service to their communities as needed. In addition, the CON standards make it very easy for new host sites to be added to existing routes, encouraging broad geographic access to this service.

Certificate of Need is also tasked with ensuring quality healthcare for the residents of Michigan. For lithotripsy, much of the quality burden lies with the technologist who positions the lithotripter and operates the equipment. With mobile lithotripsy service, the technologist travels with the

1500 West Park Drive, Suite 390
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Fax: 508-870-0682
www.ums-usa.com

unit and because of that, performs an average of 1,200 procedures per year. This is much higher than if they were to just work at a single fixed site. The highest volume site we have in Michigan performed just 763 procedures in 2011 and the average volume at a single site was just 154 procedures.

In addition, the CON regulations also ensure that lithotripsy procedures are only performed in an appropriate setting. Although lithotripsy is a non-invasive procedure, it is still a serious procedure that involves sedation and if done improperly can result in significant complications, including reduced kidney function and problems with surrounding organs, not to mention the complications that can come with any use of anesthesia. In states that do not have CON for lithotripsy services, some physicians are performing these procedures and administering anesthesia in their offices. Michigan's CON regulations require facilities to have all of the necessary staff, equipment, and supplies on-site to handle any complications.

Certificate of Need and the efficiencies that have been created in Michigan under this system have led to much lower costs for providers of lithotripsy services. Nationally, the charge by a mobile lithotripsy provider to the facility receiving service is between $2,200 and $2,400 per procedure. However, in Michigan the rate is between $1,400 and $1,500 per procedure.

Lithotripsy is an outpatient service with a high potential for abuse. Unlike MRI, CT, MRT and many other health services, lithotripsy is not considered a "designated health service" under Stark and therefore physician self-referral is not restricted under those regulations. In states that do not cover lithotripsy under their CON program or do not have CON, physicians own their own lithotripters and have a financial incentive to perform more lithotripsy procedures. CON in Michigan acts as a deterrent to every physician group owning their own lithotripter and makes it much more difficult for a single physician group to have sole direct ownership. The system still allows for some physician ownership, but encourages a situation where several groups must at least have joint ownership and, in most cases, also involves a non-physician managing partner. This acts as a deterrent for physicians who may otherwise have been lured into less than ideal schemes to bring in revenues.

We believe that health facilities, patients, and payers are all best served by the continued regulation of lithotripsy under the Certificate of Need program. I appreciate your time in considering these comments and the issue at hand. Please feel free to contact me directly with any questions at 1-800-516-9425.

Respectfully,

Jørgen Madsen
CEO

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 10:05 AM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: UMHS_CT_Public_Comments_23Oct2012.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: 912620

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Wednesday, October 24, 2012 11:23 AM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)
Attachments: UMS_Litho_Comments_10-24-12.pdf

1. Name: Jorgen Madsen
2. Organization: United Medical Systems 3. Phone: 800-516-9425 4. Email: jmadsen@ums-usa.com 5. Standards: Litho
6. Testimony:

Content-Length: 154946

UMS
UNITED MEDICAL SYSTEMS

October 17, 2012

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

Re: CON Standards for UESWL Services

Dear Chairman Falahee,

Thank you for the opportunity to provide comments regarding the Certificate of Need Standards for Urinary Extracorporeal Shock Wave Lithotripsy Services. 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. I am writing to encourage the continued regulation of UESWL services and to provide you with support for doing so.

First let me start by explaining my expertise in this area. I am the Chief Executive Officer of United Medical Systems (DE), Inc. (UMS), minority owner of Great Lakes Lithotripsy. UMS provides mobile UESWL (aka lithotripsy) across the United States. In Michigan, UMS owns and manages four mobile lithotripsy routes through several subsidiaries. UMS has been providing transportable lithotripsy services in the United States since 1998 and in Michigan since 2001.

Lithotripsy is a great example of how Certificate of Need in Michigan helps to ensure broad access to high quality healthcare services while keeping costs down. CON has encouraged lithotripsy to become a mobile service in Michigan by requiring multiple inpatient facilities to collaborate and commit MIDB data to the initiation of a new service. Because lithotripsy is not a high volume procedure at any one individual location, it is ideally suited for mobile service which has led to a more efficient and effective means of providing this service to Michigan patients. Rather than each hospital purchasing this expensive piece of equipment and only utilizing it a few days a month, they can instead obtain the services from a mobile service provider and share the costs with all of the other facilities receiving service on that route. This has resulted in an expansion from 4 fixed lithotripsy sites originally to 76 lithotripsy host sites in 2011. These sites range from large tertiary hospitals to small rural critical access hospitals, to freestanding surgery centers. The small rural facilities would never have enough volume to justify a fixed lithotripter, but because of the CON system here in Michigan, now can provide this service to their communities as needed. In addition, the CON standards make it very easy for new host sites to be added to existing routes, encouraging broad geographic access to this service.

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unit and because of that, performs an average of 1,200 procedures per year. This is much higher than if they were to just work at a single fixed site. The highest volume site we have in Michigan performed just 763 procedures in 2011 and the average volume at a single site was just 154 procedures.

In addition, the CON regulations also ensure that lithotripsy procedures are only performed in an appropriate setting. Although lithotripsy is a non-invasive procedure, it is still a serious procedure that involves sedation and if done improperly can result in significant complications, including reduced kidney function and problems with surrounding organs, not to mention the complications that can come with any use of anesthesia. In states that do not have CON for lithotripsy services, some physicians are performing these procedures and administering anesthesia in their offices. Michigan's CON regulations require facilities to have all of the necessary staff, equipment, and supplies on-site to handle any complications.

Certificate of Need and the efficiencies that have been created in Michigan under this system have led to much lower costs for providers of lithotripsy services. Nationally, the charge by a mobile lithotripsy provider to the facility receiving service is between $2,200 and $2,400 per procedure. However, in Michigan the rate is between $1,400 and $1,500 per procedure.

Lithotripsy is an outpatient service with a high potential for abuse. Unlike MRI, CT, MRT and many other health services, lithotripsy is not considered a "designated health service" under Stark and therefore physician self-referral is not restricted under those regulations. In states that do not cover lithotripsy under their CON program or do not have CON, physicians own their own lithotripters and have a financial incentive to perform more lithotripsy procedures. CON in Michigan acts as a deterrent to every physician group owning their own lithotripter and makes it much more difficult for a single physician group to have sole direct ownership. The system still allows for some physician ownership, but encourages a situation where several groups must at least have joint ownership and, in most cases, also involves a non-physician managing partner. This acts as a deterrent for physicians who may otherwise have been lured into less than ideal schemes to bring in revenues.

We believe that health facilities, patients, and payers are all best served by the continued regulation of lithotripsy under the Certificate of Need program. I appreciate your time in considering these comments and the issue at hand. Please feel free to contact me directly with any questions at 1-800-516-9425.

Respectfully,

Jørgen Madsen
CEO

Kellogg, Natalie (DCH)

From: DoNotReply@michigan.gov
Sent: Tuesday, October 23, 2012 9:40 AM
To: MDCH-ConWebTeam
Subject: October 10, 2012 Public Comment Period Written Testimony (ContentID - 147062)

1. Name: Melissa Cupp
2. Organization: Wiener Associates
3. Phone: 5173742703
4. Email: melissacupp@wienerassociates.com 5. Standards: NH 6. Testimony: I am writing to request that the Nursing Home and HLTCU Beds standards be revised to correct what I would consider a couple of technical drafting issues as follows:

1. I would recommend modifying the definition of relocation as follows:
(aa) "Relocation of existing nursing home/HLTCU beds" means a change in the location of existing nursing home/HLTCU beds from the licensed site to a different EXISTING licensed NURSING HOME/HLTCU site within the planning area.

2. I would recommend modifying Section 15(2) include projects replacing beds under the new design model within the planning area to the list of projects that do not require comparative review.

Although not technical in nature, I would also like to suggest that the Commission consider removing the limitation that only 50% of a facilities beds can be relocated to another existing licensed nursing home. This has created hurdles to moving beds out of older facilities and combining beds together in situations that would have resulted in positive projects creating new facilities and it is not clear what harm it was intended to prevent.

Thank you for taking the time to consider these comments.

Respectfully,
Melissa Cupp
7. Testimony:

Fax

To:	Brenda Rogers: Policy Area	**From:**	Ted Amland
Fax:	15172411200	**Pages:**	15
Re:	CON Written Comment for Lithotripsy Standards	**Date:**	Oct 24, 2012

X Urgent **For Review** **Please Comment** **Please Reply** **For Information**

- **Comments:**

Dear Ms. Brenda Rogers,

On behalf of Greater Michigan Lithotripsy, I am submitting the following (14) page document regarding the Public Comment Period for CON Review of the Lithotripsy Standards.

I tried unsuccessfully for 30 minutes to submit through the online website, but continued to receive an error on the page. We spoke with Sally Flanders and she recommended faxing this to your attention.

Respectfully,

Ted Amland

Vice President of Operations

Greater Michigan Lithotripsy

P: (614) 298-8150 ext. 24

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October 24, 2012

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October 24, 2012

James B. Falahee, Jr., Chair
Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Mr. Falahee,

This letter is written as formal testimony concerning the CON Review Standards for UESWL Services. Greater Michigan Lithotripsy (GML) supports continued CON regulation of lithotripsy services and would like to take this opportunity to comment on these Standards.

A. Background

GML is a partnership involving hospitals and physicians established to provide mobile Urinary extracorporeal shock wave lithotripsy (UESWL) services to the citizens of Michigan. We are involved in three (3) mobile lithotripsy routes in the state, serving more than two (2) dozen host sites in Lower Michigan. **We are concerned that the number of cases required to expand the number of lithotripsy units on a mobile route is excessive and results in insufficient access to this service for the residents of the state.**

UESWL is the most frequently used treatment for patients with kidney stones. It involves the generation of shock waves outside the body, which travel through the skin and internal tissue until striking the stone located in the kidney or ureter. Fragmentation of the stone allows for the small particles to pass normally through the urinary tract. Since its introduction in 1984, technological advancements have taken place which now allow for treatment of calculi located not just primarily in the kidney, but throughout the ureter as well. Since the adoption of UESWL for ureteral stones, the demand for UESWL has increased by 25%. Recovery time is actually short and patients generally resume normal activities in a few days.

B. Case load data

We have asked our management company, AKSM, Ltd., to review their national case loads to determine the typical volume for mobile lithotripters. AKSM is the country's second largest lithotripsy service provider and manages over 60 mobile and fixed-site lithotripters for some 18 independently-owned companies across the country. Nationwide, on average, a mobile lithotripter performs 500 cases per year. The maximum number of cases performed on any single mobile lithotripter is 1,264 cases. As a general rule anywhere with no CON regulations, once case volume exceeds 1,000 cases per machine, a second lithotripter is added to a mobile route.

An important reason a mobile route adds a second lithotripter is because a single mobile lithotripter treating more than 1,000 cases annually, is subject to increased down time for maintenance and is unable to be physically transported in a timely fashion to satisfy the required demands of dispersed communities. If another machine is not added to a high volume route, the result is that patients have their treatments postponed or are treated invasively. GML does not feel that this is providing the best quality of care to the patients we serve.

C. Increased access = better quality of care

GML has an immediate need for two (2) additional mobile lithotripters, in order to better serve our currently contracted facilities. Although performing fewer than 1,800 procedures, we are at capacity on all of our routes and frequently can't meet the demand for timely patient treatments. The additional machines would provide more than 1,000 non-invasive UESWL procedures at eighteen (18) hospitals. Currently at these hospitals, urologists often are forced to perform invasive ureteroscopic procedures for stone removal, because of a lack of access to machines.

A ureteroscopic stone procedure for a male involves passing a ureteroscope into the penis, through the urethra and bladder and into the ureter. For a female, it can be likened to having a catheter insertion. This procedure is far more risky to the patient than UESWL, in terms of infection and possible ureteral injury, and results in higher costs due to the need for additional staffing and supplies.

D. Access in rural areas

This issue is particularly acute in rural areas, where mobile units visit less frequently because of smaller populations. As a result, patients in rural areas may have to wait for two to four weeks to obtain needed lithotripsy services. In such cases, the physician may opt to insert a urethral stent as a temporary measure until the lithotripsy machine becomes available or alternatively the urologist may perform an invasive ureteroscopic procedure as previously described. A CON adjustment factor applied to the need and volumes in rural areas would help to address the rural access issue and would make the CON Standards more responsive to the needs of residents of rural Michigan.

E. Preventive and emergency maintenance

The restrictive requirements for expansion of the number of lithotripsy machines on a mobile route do not allow for downtime, either emergency or scheduled. To ensure patient safety, GML has very strict guidelines to perform Preventative Maintenance (PM) on a quarterly basis. Typically quarterly PM takes at least eight (8) hours to complete. If PM is not completed diligently, risk is increased for equipment failure, which affects timely service to patients in need of treatment.

The CON requirements also make no provisions for the mobile provider to utilize temporary equipment while necessary repairs are made. Many situations require replacement parts to be shipped, which can result in an extended period of time during which lithotripsy services are unavailable. On very busy mobile routes serving multiple rural sites on a very infrequent basis, unavailability of the mobile unit for a week or more, can result in long delays for patients requiring lithotripsy or substitution of more invasive, higher risk surgical procedures. Simply for maintenance and breakdowns alone, it makes good business sense to add a machine to rotate for these purposes. A provision under CON for the use of a temporary lithotripsy unit during downtimes for repairs, without having to apply for an emergency CON, would help to address this concern.

Alternatively, the need for temporary back-up equipment to cover downtime could be met if existing providers were allowed to cross over HSA boundaries. When these unplanned downtime events occur, current CON provisions prohibit any other machine operated by the same provider from servicing that area. Oftentimes there is an available machine in the adjacent HSA, which could easily perform those treatments. GML experienced this very situation this past year, when over a dozen cases had to be canceled due to unanticipated downtime and a mobile unit from a different route was available to meet the demand.

F. Summary

In light of the nationwide experience of our partner, AKSM, we believe that the CON requirement for expansion of an existing mobile lithotripsy route, 1,800 procedures per unit annually, is excessive. With approximately 254 business days in a year, this means that a **mobile route would be required to treat a minimum volume of 7 cases every day.** This is highly improbable given the CON guidelines of using only one machine per route, downtime, geography and volume fluctuations.

Therefore, we recommend the following changes to the CON guidelines:

1. The volume requirement to expand a mobile route be reduced to 1,200, which is more consistent with national experience, as cited above.
2. A rural adjustment factor of two (2) be applied to rural host sites, both those currently providing lithotripsy and those applying to initiate the service.
3. Allowance for using a temporary lithotripsy unit during downtimes for repairs, without having to apply for an emergency CON. This could potentially be addressed by allowing existing units to cross HSA boundaries.

GML appreciates the opportunity to comment on the CON Review Standards for UESWL, and we urge that the CON Commission initiate a process to revise these Standards. We are willing to participate in this process as appropriate.

Sincerely,

Ted Amland
Vice President of Operations
Greater Michigan Lithotripsy

HealthCare
Midwest
Work with us in partnership for a lifetime of good health.

Urology
The Continence Center
Gregor W. Blix, MD
James B. Bour, MD
Anthony R. Gauthier Jr., MD
Robert R. Isacksen, MD
Mark A. Lucas, MD
Brandon S. Rubens, MD
Charles P. Roelant, PA-C
Susan Creager, MSN, CNS, BC
Donna Pennington, MSN, FNP, BC
Lita Martin, MSN, FNP-C

Downtown Office
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Gull Road Office
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October 23, 2012

James B. Falahee, Jr., Chair
Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

RE: ESWL C.O.N. Review Standards

Dear Mr. Falahee:

I am a practicing urologist with HealthCare Midwest Urology. I primarily treat patients who have kidney stones at Bronson Methodist Hospital utilizing non-invasive lithotripsy (ESWL) supplied by an excellent service provider. Unfortunately, I am unable to utilize lithotripsy services as often as my patients require because my hospital has limited access to lithotripsy equipment.

I understand the reason for this limited access is because the current C.O.N. standards restrict my lithotripsy provider's ability to purchase additional lithotripters for its mobile routes. I support efforts to alter the C.O.N. standards to allow it to acquire additional lithotripters.

When my patients do not have access to non-invasive lithotripsy, the alternative treatment is invasive surgery, with its attendant complications. Please seriously consider this request.

Sincerely,

Gregor W. Blix, M.D.

GWB: klk D: 10/23/12 T: 10/23/12

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Sincerely,

Brandon S. Rubens, M.D.

BSR: klk D: 10/23/12 T: 10/23/12

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Sincerely,

Anthony R. Gauthier, M.D.

ARG: klk D: 10/23/12 T: 10/23/12

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Sincerely,

M A Lucas, MD

Mark A. Lucas, M.D.

MAL: klk D: 10/23/12 T: 10/23/12

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October 23, 2012

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Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

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When my patients do not have access to non-invasive lithotripsy, the alternative treatment is invasive surgery, with its attendant complications. Please seriously consider this request.

Sincerely,

Suresh Potluri, M.D.

SP: klk D: 10/23/12 T: 10/23/12

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October 23, 2012

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C/o Michigan Department of Community Health
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Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

RE: ESWL C.O.N. Review Standards

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Sincerely,

Robert R. Isacksen, M.D.

RRI: klk D: 10/23/12 T: 10/23/12

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C/o Michigan Department of Community Health
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Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

RE: ESWL C.O.N. Review Standards

Dear Mr. Falahee:

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I understand the reason for this limited access is because the current C.O.N. standards restrict my lithotripsy provider's ability to purchase additional lithotripters for its mobile routes. I support efforts to alter the C.O.N. standards to allow it to acquire additional lithotripters.

When my patients do not have access to non-invasive lithotripsy, the alternative treatment is invasive surgery, with its attendant complications. Please seriously consider this request.

Sincerely,

J Bour

James B. Bour, M.D.

JBB: klk D: 10/23/12 T: 10/23/12

ADVANCE UROLOGY
HECTOR Y. RODRIGUEZ, M.D.
Diplomate American Board of Urology

LEVAN MEDICAL CENTER
15138 Levan Road, Suite 38
Livonia, MI 48154
Telephone: (734) 779-2133
Fax: (734) 779-2135

October 23, 2012

James B. Falahee, Jr., Chair
Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

RE: ESWL C.O.N. Review Standards

Dear Mr. Falahee:

I am a practicing urologist. I treat patients who have kidney stones at the Providence Park Hospital utilizing non-invasive lithotripsy (ESWL). Unfortunately, I am unable to schedule the lithotripsy services as often as required by my patients because that hospital has limited access to the lithotripsy equipment. I understand the reason for this limited access is due to the current C.O.N. standards which restrict the lithotripsy provider's ability to purchase additional lithotripters for its mobile routes.

When my patients do not have access to non-invasive lithotripsy, the alternative treatment is invasive surgery, with increased exposure to additional complications.

I support efforts to alter the C.O.N. standards to allow this provider to acquire additional equipment to satisfy the treatment demands for my area.

Sincerely,

Hector Y. Rodriguez, M.D.

WEST SHORE UROLOGY, P.L.C.

JOSEPH A. SALISZ, M.D.
KEVIN T. STONE, M.D.
BRIAN R. STORK, M.D.
CALEB J. FLEMING, M.D.
MICHELLE L.HASS, PA-C
CLAY W. REEVES, NP-C

1301 MERCY DRIVE
MUSKEGON, MICHIGAN 49444-1837
PHONE (231) 739-9492 • FAX (231) 733-5376

October 24, 2012

Dear Mr. Falahee:

I am a practicing urologist with West Shore Urology, PLC. I primarily treat patients who have kidney stones at Hackley Hospital, North Ottawa Community Hospital and Muskegon Surgery Center utilizing non-invasive lithotripsy (ESWL) supplied by an excellent service provider. Unfortunately, I am unable to utilize lithotripsy services as often as my patients require because my hospital has limited access to lithotripsy equipment.

I understand the reason for this limited access is because the current C.O.N. standards restrict my lithotripsy providers ability to purchase additional lithotripters for its mobile routes. I support efforts to alter the C.O.N. standards to allow it to acquire additional lithotripters.

When my patients do not have access to non-invasive lithotripsy, the alternative treatment is invasive surgery, with its attendant complications. Please seriously consider this request.

Sincerely,

Dr. Joseph Salisz

Dr. Brian Stork

Dr. Kevin Stone

SPECTRUM HEALTH

Spectrum Health Reed City Hospital
300 N Patterson Road
Reed City, MI 49677

October 23rd, 2012

James B. Falahee, Jr., Chair
Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building,
201 Townsend Street
Lansing, Michigan 48913

Dear Mr. Falahee,

Spectrum Health Reed City Hospital currently receives mobile lithotripsy services one time per month. This schedule is insufficient to meet the needs of our patients as we are only able to meet the needs of approximately 8 patients per month. While we support continued CON regulation of lithotripsy services, we strongly urge the CON Commission to reduce the volume requirement for expanding the number of lithotripsy machines that can serve our patients. Without reducing the expansion criteria from its current unrealistic level of 1800 procedures per year, our mobile service provider will not be able to increase our access to lithotripsy services, causing more of our patients to undergo risky and costly invasive procedures to alleviate the painful condition of kidney stones. This is a patient safety issue.

Thank you for the opportunity to comment on this matter which is of great importance to our physicians and patients.

Sincerely,

Scott Lombard, RN, BSN
Director of Nursing Operations and Patient Safety Officer

GROSSE POINTE UROLOGY

DIVISION OF COMPREHENSIVE MEDICAL CENTER, PLLC

THOMAS J. MERTZ, M.D.
DINESH J. TELANG, M.D.
TODD G. CAMPBELL, M.D.
PYARA S. CHAUHAN, M.D.
JEFFREY C. YEAMANS, M.D.
KEVIN M. FEBER, M.D.
NORMA F. LOWERY, N.P.

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PEDIATRIC
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SUITE 103
FENTON, MI 48430
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October 22, 2012

James B. Falahee, Jr. CON Commission
C/O Michigan Dept. Of Community Health
Certificate of Need Policy Section, Capitol View Bldg.
201 Townsend St.
Lansing, MI 48913

RE: ESWL CON Review Standards

Dear Mr. Falahee:

I am a practicing urologist with Comprehensive Urology. I primarily treat patients who have kidney stones at Beaumont Grosse Pointe utilizing non-invasive lithotripsy (ESWL) supplied by an excellent service provider. Unfortunately, I am unable to utilize lithotripsy services as often as my patients require because my hospital has limited access to lithotripsy equipment.

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Sincerely,

Thomas J. Mertz, M.D.

Dinesh J. Telang, M.D.

Todd G. Campbell, M.D.

Jeffrey C. Yeamans, M.D.

Philip J. Shalhoub, M.D.