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Testimony by Xoran Technologies Inc.
February 6, 2008 MDCH Public Hearing on Proposed CON CT Standards Changes

Dear CON Commission:

Good morning, my name is Matt Jordan, and I am testifying on behalf of Xoran Technologies Inc. regarding the proposed Michigan Certificate of Need (CON) changes to the CT Standards. I appreciate the opportunity to testify before you today.

Xoran Technologies Inc., based in Ann Arbor, MI, is a world-class developer of specialty-use CT scanners primarily used by ear, nose, and throat (ENT) physicians. Our main product is the MiniCAT™, a low-cost, low-radiation dose specialty CT scanner designed for in-office use. It the combination of lower cost and in-office use of these specialty CT scanners that sets our products apart from traditional CT scanners. By bringing a $230,000 limited use specialty CT scanner to ENT physicians in their office, patients and physicians have an opportunity to achieve better, faster, and safer diagnostic imaging that is vital to treatment. And yet despite the promise of this technology and its availability in 47 other states without the requirements of a certificate of need application, Michigan remains just one of three states that effectively prohibit this in-office specialty CT due to restrictive CON regulations. Simply put, the requirement that all CT CON applicants, regardless of the type of equipment, demonstrate 7500 equivalent CT scans in order to achieve CON approval, effectively prohibits any ENT physician and most hospitals from acquiring a low-cost, low-dose specialty CT scanner. Both the current and proposed CON CT Standards do not consider this emerging technology, and we ask that the CON Commission reconsider this vital use of specialty CT scanners.

We believe that the approach that 47 other states have taken towards exempting low-cost, low-dose specialty CT scanners is the most effective and least restrictive manner to achieving a balance of cost, quality, and access when it comes to this diagnostic equipment. Of the states that retain CON regulations, the majority exempt low-cost, low-dose specialty CT scanners from CON regulations by setting a dollar threshold related to the equipment. These states exempt CT scanners from CON by stating that CT scanners and medical equipment costing, for example, below $750,000 (North Carolina), do not have to file for a CON application. Recently, West Virginia went further by approving new CON CT regulations in January 2008 that specifically exempt a low-dose CT scanner from CON that costs below $2 million and has either a radiation dose output of less than 1.0 millisieverts or a power output below 5 kilowatts. Xoran believes this is the best manner to achieve the goals of the CON program and yet still adapt regulations to the ever-changing advances in healthcare.

Xoran urges the CON Commission to make a change to the proposed CON CT Standards now before the Commission. In the definition of a CT scanner in Section 2 (i), the following language should be added:

"The term (CT Scanner) does not include CT scanner systems that both generate a peak power output of 5 kilowatts or less and costs less than $500,000".

We believe that this change will remove CON regulations from low-dose, low-cost specialty CT scanners just as most of the rest of the nation has chosen to do so, while still allowing Michigan to apply CON regulations to the healthcare additions that matter: large capital expenditures and procedure-intensive

equipment. Michigan has already chosen to not regulate other low-cost medical equipment used in-office, most notably ultrasound, kidney dialysis equipment, and digital two-dimensional x-ray machines. Specialty CT scanners used in-office more closely align with the purpose and cost of these unregulated equipment and thus should be treated in the same manner in excluding from CON regulations.

We appreciate both the CT Standard Advisory Committee (CTSAC) and the CON Commission in permitting Xoran to testify in the past six months about this important and emerging technology. However, we feel that all the factors surrounding in-office specialty CT scanning have not been fully discussed. THE CTSAC did not inquire into the benefits of limited use CT scanning for in-office applications, but instead chose to vote against the concept with little discussion. The end result is that ENT physicians in Michigan are prohibited from acquiring these specialty CT scanners for their offices, patients are blocked from access to lower radiation dose CT scanning despite national calls to limit x-ray exposure, and a Michigan company, Xoran, is unable to sell its equipment in its own home state. What is particularly difficult to understand is that despite being granted over $7 million from the Michigan Economic Development Corporation (MEDC) and being named one of the "50 companies to watch" by Governor Granholm, Xoran is effectively unable to sell its MiniCAT™ in-office CT scanner in Michigan. We feel that all of these factors must be considered by the CON Commission when deciding on the proposed CT Standards and that the right choice for our state would be to exempt low-cost, low-dose specialty CT scanners from the CON process with the language above. The benefits to allowing in-office CT scanning outside the CON process far outweigh any risks, and would improve the state's healthcare environment for physicians, patients, employees, and employers across the board. Additionally, other methods of controlling the proper use of CT scanners will still remain, as CT scanners used in-office will still have to achieve the requirements of the Michigan Radiation Safety Section, must still be approved by insurance companies via prior authorization for scans, and must meet the accreditation requirements developed and rolled out nationally by both the American College of Radiology (ACR) and the Intersocietal Accreditation Commission (IAC). We again urge the CON Commission to make this necessary change to the proposed CON CT Standards now before you and permit in-office CT scanning by ENT physicians.

Thank you for allowing me to testify before you, and I look forward to any questions and comments that you may have on this important matter.

Sincerely,

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States that Regulate Computed Tomography (CT) Scanners

	Which States exempt specialty CT scanners under CON?	How do these states exempt specialty CT scanners?	What is the dollar threshold, below which a CON is NOT required?
Alaska	☑	Dollar Threshold	$1,000,000
Connecticut			N/A
Georgia	☑	Dollar Threshold	$875,018
Hawaii	☑	Dollar Threshold	$1,000,000
Maine	☑	Dollar Threshold	$1,200,000
Michigan		Special language for dental scanners only	N/A
Missouri	☑	Dollar Threshold	$1,000,000
New Hampshire	☑	Dollar Threshold	$400,000
New York	☑	Dollar Threshold	$3,000,000
North Carolina	☑	Dollar Threshold	$750,000
Rhode Island	☑	Dollar Threshold	$1,000,000
Tennessee	☑	Dollar Threshold	$1,500,000
Vermont	☑	Dollar Threshold	$1,000,000
Virginia			N/A
West Virginia*	☑	Dollar Threshold AND either Radiation Threshold or power output (approved 01-18-2008)	$2,000,000*

☑ = Yes

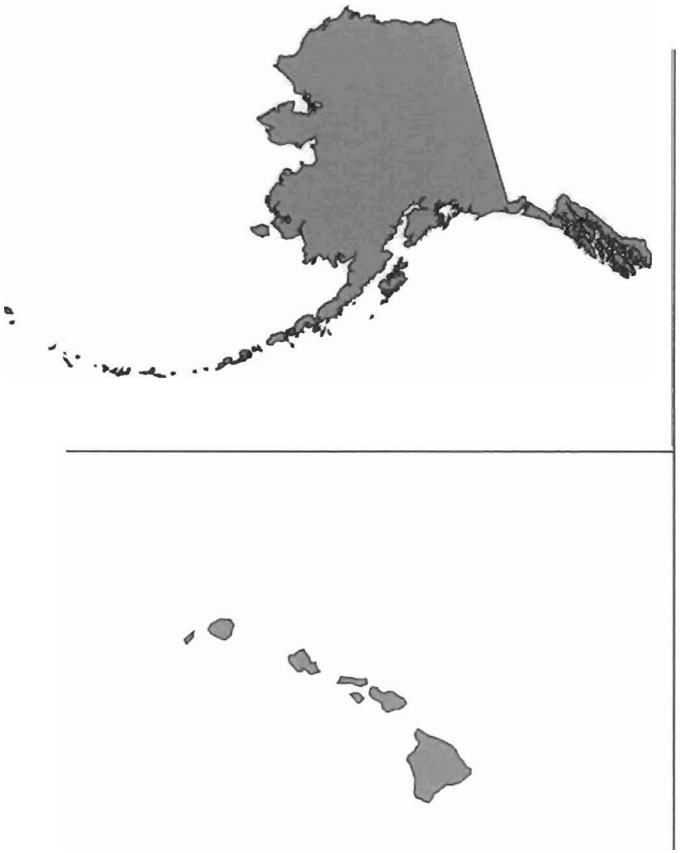
*** West Virginia threshold exempts CT that is below $2 million AND either below 1.0 mSv radiation dose or below 5 kilowatts of peak power**

Note: The 35 remaining states do not regulate CT scanners directly; only 10 states of the 35 remaining states indirectly regulate CT scanners as Medical Equipment in general, and CON is only required if cost is above $600,000 (Medical Equipment threshold spread: low, Wisconsin $600,000; high, Illinois $6,575,036)

Sources: AHPA Survey, 2005; National Conference of State Legislators, www.ncsl.org

States that require a Certificate of Need (CON) filing for low-cost, low-dose CT scanners used in-office

Green = No CON filing needed
Red = CON required regardless of cost or location of use



Source: http://www.ncsl.org/programs/health/cert-need.htm

The Economic Alliance for Michigan
CON Commission Public Hearing
February 6, 2008

Dennis McCafferty, Health Policy Director

CT scanner Services:

We strongly agree with the position recommended by the Special Advisory Committee and accepted by the Commission at their December 2007 quarterly meeting that all CT Scanners should continue to be subject to CON.

We also support and endorse the many other improvements in the CT Scanner CON standards proposed by the SAC and accepted by the Commission, including:

- The minimum annual volume number of scan equivalents is unchanged at 7500.
- Replacement for existing CT Scanners can only be done if current machine has met this minimum annual volume at some time since its inception AND now is providing at least 5,000 CT equivalents.
- Projecting the need for new CT scanner sites based on actual, historically referrals volumes that can be verified by MDCH through its annual survey. **(We consider this a *Major improvement over existing standards.)***
- That projection of need for new CT scanners cannot use referrals that would result in lowering an existing CT scanner below its minimum CON volume requirements. **(We consider this to also be a *Major improvement over existing standards.)***
- Approval of a Demonstration Project for Special Use Portable CT's, limited to major trauma centers that have experienced staff on site to maintain, operate and interpret the results. The scans on these special use units will not be counted as part of the hospitals' other CT scanner equivalent scan totals. **(Reasonable constraint of this new technology, limiting use to existing high-volume imaging centers that will enable qualified providers to evaluate what value these portable CT units may provide the patients and treating physicians.)**
- Continued CON regulation of dental office CT at the same annual minimum volume and services approved by the Commission in 2006.

CON Public Hearing
Nursing Home and HLTCU
Review Standards
February 6, 2008

Good Morning!
I am Pat Anderson representing the Health Care Association of Michigan. HCAM is a statewide trade association representing 240 skilled nursing and rehabilitation facilities caring for nearly 24,000 of Michigan's frail elderly and disabled adults. HCAM represents proprietary, non-proprietary, county medical care facilities and hospital long term care units. Our membership employs over 30,000 dedicated caregivers providing quality care every day of the year.

HCAM has participated in the Nursing Home and Hospital Long Term Care Unit (HLTCU) Standards Advisory Committee (SAC) reviewing the Certificate of Need (CON) review standards for nursing home and HLTCU. We also participated in the Quality Measure Workgroup that was formed by the CON Commission at their December meeting. HCAM appreciated the Commission's efforts to establish the workgroup to provide us additional time to come to a consensus on an amendment to the SAC proposed Quality Measures.

HCAM is supportive of the Quality Measures crafted by the workgroup at their January 2008 meetings. The HCAM Board of Directors at their January meeting expressed support of these measures as a starting point for addressing quality in the CON process. HCAM continues to have concerns about relying heavily on the survey process as the primary indicator of quality of care. The survey process was designed to address regulatory compliance issues and not as a measure of quality. HCAM continues to support the customer and their satisfaction as the best indicator of quality of care.

HCAM is supporting the proposed CON Nursing Home and HLTCU's review standards labeled "with Proposed Amendment." HCAM does have a few technical clarifications and consistency issues that need to be addressed. Our concerns are presented by each Section of the standards.

Section 1 Applicability
- No comment

Section 2 Definitions
- No comment

Section 3 Determination of needed nursing home bed supply
- No comment

Section 4 Bed need

- Item 4 of this section refers to the effective date of the newly computed bed need based on the updated 2006 cohorts and population projections from 2010. HCAM is concerned about when the new bed need is effective and its impact on current CON applications and those issues that are under appeal. How will the effective date take into account these issues?

  HCAM would propose that it seems reasonable to have the effective date be 6 to 9 months in the future to allow for any existing appeals or other issues to be resolved before implementation of the new bed need.

- The new bed need utilized the projected population data for the year 2010. It is interesting to note that in Macomb County if the bed need was set on the 2005 data it would show 463 fewer beds. This would indicate a tremendous increase in aged population in this County in the five year time span. HCAM would like to know how the projections were developed.

Section 5 Modification of age specific use rates by changing the base year

- No comment

Section 6 Requirements for approval to increase beds in a planning area

- Part 1 (B) line 336 requires an applicant at the time of application to have certified that the Minimum Design Standards for Health Facilities will be met when the construction plans are submitted for review and approval by the Department. This seems unnecessary because the applicant must comply with the design standards under the licensure provisions of the Public Health Code (part 201).

  HCAM would like to request that item 1(B) be removed due to the redundancy of requiring it twice and a timing issue. At the time of application the architectural plans typically have not been approved by the Department. The plans will be approved prior to licensure which is the appropriate time during the construction.

- Part 1 (C) line 341 addresses the need for a Plan of Correction (POC) for any deficiencies resulting from a survey. HCAM is concerned with the timing of when a facility is notified by the Bureau of Health Systems regarding survey deficiencies, when a POC is due and when the Bureau is able to approve the POC. We would suggest some minor changes to maintain the intent of this part while overcoming some timing delays that are occurring with the processing of the survey results.

HCAM would suggest the following wording for this item:

1(C) A written Plan of Correction for cited State or Federal code deficiencies at the health facility, if due for submission, has been submitted to the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department.

- Part 2 (C) line 454 was changed from single occupancy rooms to beds. HCAM would request that this be changed back to rooms to be consistent with similar language contained in the comparative review criteria (table on line 886).

  HCAM is also requesting that the at least 80% single occupancy room requirement be changed to at least 50% single occupancy rooms. The lowering of the percentage will substantially reduce the cost of construction. This cost reduction will allow those nursing facilities that serve a higher Medicaid resident population to access sufficient capital that is closer to the Medicaid reimbursement limits.

  HCAM would suggest the following wording:

  2 (C) The proposed project shall include at least 50% of the rooms be single occupancy resident rooms with an adjoining bathroom serving no more than two residents in both the central support inpatient facility and any supported small resident housing units.

Section 7 Requirements for approval to relocate existing nursing home/HLTCU beds

- Part 1 (D) provides a limitation on the frequency of beds that can be relocated under this standard. HCAM supports this change to accommodate changing population within planning areas but feel the 7 years limitation is overly restrictive. HCAM would propose a modification to this standard to permit bed relocations every 2 years.

  The Michigan Medicaid program has a policy that allows a nursing facility to take beds off-line titled "Beds Out of Service Policy". This policy contains a two year limit to the length of time the beds can be out of service, then they must be either put back into service, removed or the facility suffers the consequence of being impacted by the 85% minimum occupancy policy. It would be consistent to align the relocation bed standards with this policy.

  HCAM would suggest the following wording:

1 (D) The nursing home/HLTCU from which the beds are being relocated has not relocated any beds within the last two (2) years.

- Part 2 (B) lines 521 makes reference to the submission of a POC. HCAM would suggest the same changes be made to this Section as in Section 6 line 341.

Section 8 Requirements for approval to replace beds

- Part 1 (D) and (E) lines 572 – 580 are issues that were addressed in Section 6 and any changes should be carried through in this section for consistency.

- Part 2 (D) and (E) lines 621 – 629 are issues that were addressed in Section 6 and any changes should be carried through in this section for consistency.

- Part 3 (B) refers to single occupancy beds and the change requested to this language in Section 6 should be carried through to this section.

Section 9 Requirements for approval to acquire an existing nursing home/HLTCU or renew the lease of an existing nursing home/HLTCU

- Part 1 (E) lines 726 – 729 and Part 3 (C) lines 786 – 789 are issues that were addressed in Section 6 and any changes should be carried through to this section.

Section 10 Review standards for comparative review

- The changes in this section tend to provide a level playing field for both the existing facility and a proposed new construction. The exception to the level playing field occurs when the standards references utilizing the most recent 12 months of facility history. A new construction can not meet this requirement because they do not have a history. This does not allow them a reasonable opportunity to succeed in the review.

  HCAM would request that the language be added to include a certification or written commitment by the facility of their willingness to participate in the Medicaid and Medicare programs including the percent of participation. The language would need to be added to lines 803, 829 and 832.

- Part 8 table on the facility design should be changed to be consistent with Section 6 to 50% single occupancy rooms. Also, what is an "adjacent private changing room"? Is this another room or space?

Section 11 Project delivery requirements – terms of approval for all applicants
No comment

Section 12 Department inventory of beds
- No comment

Section 13 Wayne county planning areas
No comment

Section 14 Health Service Areas
- No comment

Section 15 Effect on prior CON review standards, comparative reviews
- Part 2 (B) references replacing an existing nursing home/HLTCU within two miles of the existing nursing home/HLTCU. HCAM requests that the two mile limitation be changed to planning area.

Thank you for the opportunity to comment on these standards. Our Michigan citizens who receive care in these facilities need to be remembered and each change should be carefully evaluated based on the resident's quality of life and quality of care.

Respectfully,
Patricia Anderson
Health Care Association of Michigan

Testimony on behalf of MAHSA on the proposed CON Review Standards for NH-HLTCU Beds February 6, 2008

MAHSA
ONE VOICE.
ONE MISSION.

My name is David Herbel, President and CEO of the Michigan Association of Homes and Services for the Aging. MAHSA represents more than 200 members of charitable, religious and fraternal organizations which provide the full continuum of long term care services to Michigan seniors.

While MAHSA is supportive of the revised quality measures and a number of updates to the nursing home standards, we believe that the amended standards before you still contain a number of shortcomings that will negatively affect access to quality nursing home services.

Those concerns include:

The High Occupancy Standard

MAHSA is extremely disappointed the NHSAC choose not to revise the high occupancy standard in a manner that benefits all nursing homes.

Currently, a nursing home that maintains 97 percent occupancy for 3 years cannot expand unless all other nursing homes in its entire planning area have had the same experience. Not only is this practice poor public policy it is contrary to the principles of consumer choice.

The Department told the NHSAC that of Michigan's 433 nursing homes, 10 met the 97 percent occupancy requirement for the last 12 quarters, but not one met the planning area criteria. Thus, none of those 10 facilities would be eligible for expansion under the existing high occupancy standard.

MAHSA urges the Commission to stop the practice of driving consumers into empty beds—regardless of quality—and afford our seniors better choices by allowing high occupancy providers—who meet the quality measures—the ability to expand.

PROPOSAL: MAHSA requests the Commission eliminate the high occupancy trigger contained in Sec. 6. (Lines 370-373 in the Feb. 6, 2008, with Proposed Amendments document).

The Phase Out of Religious Use Beds

The NHSAC's decision to phase out the special pool of religious use beds is deeply concerning to several MAHSA faith-based organizations—many with historical roots dating back hundreds of years, such as

Evangelical Homes of Michigan and United Methodist Retirement Communities.

This small, special pool of beds allows our faith-based constituencies to obtain nursing home care in centers dedicated to their religious needs. Hundreds of seniors receive care near their place of worship because of these beds. As you are well aware, Michigan's 85+ age group is increasing faster than any other demographic, and the need for more beds dedicated to serving the needs of faith-based citizens will grow as well.

This religious use pool of approximately 300 beds has historically been used by charitable religious members to create new ministries based on the movements of their congregations. These organizations were established for a specific purpose for serving a quantifiable number of church members who wish to live out their lives consistent with their beliefs.

PROPOSAL: MAHSA urges the Commission not to phase out the use of religious beds in the Addendum for Special Population Groups.

A New Policy to Relocate Existing Beds

Generally, Nursing Homes are not allowed to split and sell portions of a license between providers. Traditionally, the provider who has extra beds returns them to the statewide pool at no cost. MAHSA opposes the proposed language for the following reasons:

- Neither the donor nor the recipient facility would need to satisfy the new quality measures to be eligible for the relocation of beds.

- The existing language will only promote the expansion of existing facilities vs. the development of new and smaller innovative design models, because it only allows the relocation of beds to currently-licensed sites.

PROPOSAL: MAHSA opposes the language Section 7 and urges the Commission to eliminate it.

Acquisition of Existing Nursing Homes
And Medicaid Participation and Comparative Review

At the Dec. 10 hearing, attorney Brian Kaser made two very important points regarding the acquisition of existing nursing homes and the Medicaid participation and comparative review that MAHSA fully supports.

By changing the definition of "acquisition of an existing nursing home" the NHSAC has proposed a system that will prevent the sale of any facility that has a license but is not operating. As Mr. Kaser's testimony indicated, facilities go out of operation for numerous reasons that are not regulatory or quality related (i.e. the death of an owner).

On the issue of Medicaid participation and comparative review, Mr. Kaser makes the point that only existing nursing homes will be able to prevail in comparative reviews over new providers due to changes the NHSAC recommends in sections 10(2) and 10(3). MAHSA urges the Commission not to allow the standards to move in this direction. Michigan desperately needs innovation in nursing

home care and incentives for providers to create new centers with a continuum of services so that our seniors may age in place as they desire.

PROPOSAL: Issue 1: Allow any licensed facility to be transferable up until its license is revoked and all avenues of appeal are exhausted. Issue 2: Restore the prior text, which evaluated applications and their projected services, rather than the past payor mix of their proponents.

In conclusion, I wish to thank the CON Commission for its consideration and willingness to readdress the quality measures issue through a workgroup process. Unfortunately, the debate over the quality measures greatly overshadowed the other access concerns our members are equally concerned with in the proposed standards. MAHSA fully supports the Commission's desire to inject quality into the CON process. We believe the revised quality measures agreement takes Michigan in the right direction. Now that that controversy seems to have been resolved, MAHSA's hope is that you will look closer at the issues of access and consumer choice that we have outlined above and make the proposed revisions to the standards at your March meeting.

Thank you for your consideration, and should you have any questions please feel free to contact me at (517) 323-3687 or by e-mail at dherbel@mahsahome.org

Respectfully submitted,

David E. Herbel
President and CEO
MAHSA

PUBLIC HEARING TESTIMONY
Nursing Home/ HLTCU
CON REVIEW STANDARDS
February 6, 2008
Submitted on Behalf of Tendercare (Michigan), Inc.

Hello
My name is Jonathan Neagle and I am here today representing Tendercare, Michigan, Inc. As the Area Vice President for Tendercare, Michigan, Inc. and Extendicare Health Services, Inc., I personally wish to thank you for the opportunity to express our opinions about the proposed Certificate of Need Review Standards.

Tendercare, Michigan, Inc is a statewide provider of long-term care through our skilled nursing facilities and our inpatient rehabilitation hospital in Michigan. Combined we provide quality, clinically based services to over 3,341 residents in the State of Michigan. Nationally, through our parent corporation Extendicare Health Services, Inc and its affiliates and subsidiaries, we provide on a daily basis care to over 19,145 residents in our 165 facilities across the United States. Extendicare Health Services, Inc with its acquisition of Tendercare, Michigan, Inc in October, 2007 is pleased to have a presence in the State of Michigan and looks forward to many years of continuing to provide optimal care to the residents of the State of Michigan.

As the Commission moves forward with an examination of the proposed Standards we urge that the goal remain focused on improving the quality of life and care for our residents. It is important to remember that such improvements can come about not only by implementation of stringent restrictions, but also by initiatives that help foster, encourage and provide incentives for Providers to engage in needed improvements whether by relocations, renovations or replacement of facility infrastructure. It is the delicate balance of both the positive initiatives and the restrictions that provide often the best outcomes. Tendercare cites the FIDS program as an excellent example of a program that provided such a balance.

Tendercare had a representative in attendance at the January 2008 workgroup on Quality Measures and wish to express our support of the Quality Measures that resulted from the January, 2008 meeting. Nonetheless, while we are supportive of the proposal that came forth from the workgroup, we still remain concerned and dismayed at the stringent use of the survey process as a measure of quality. In addition, we still believe that the best type of changes to a process (those that have the most benefit and success) are those implemented in slow and incremental ways. We continue to assert that the standards developed to date proceed in a manner that implements new criteria in a way that is not indicative of a slow and increment process, at all. With that said, we still wish to reiterate that we do support the standards for Quality Measures as was brought forth from the January, 2008 meeting of the workgroup.

In addition, while we support the workgroup proposal that was brought forth there does clearly and definitively exist a number of issues in the proposed Standards that Tendercare asserts to be in need of further revision, clarification and/or alteration.

As I take a moment to outline our concerns and comment, I will be referring to sections and line numbers as contained on the CON Review Standards for Nursing Home and HLTCU Beds with Proposed Amendments.

Minimum Design Standards for Health Facilities:

In Section Six, line 336-340, (Section 6, 1, B, page 7), Section Eight, line 572-576 (Section 8, 1, D page 12) and Section 8, lines 621-625, (Section 8, 2, D page 13) a CON applicant will be required to certify compliance with the Minimum Design Standards for Health Facilities in the initial plans. The Minimum Design Standards are required to be met already under the licensure provisions of the Public Health Code. Inserting them in the CON standards is not only redundant, but not inconsistent with the flow of construction projects and the timing of submission of architectural plans and revisions. The resulting effect could be an applicant who certifies that they are in compliance but later is determined to not be in compliance by the Department at the time of the submission of the architectural plan. This could occur, for example, at the time the construction permit is being issued. Further this could occur at a time significantly after the date the CON is issued. As a result, a CON applicant, who now has an approved CON, could be deemed to be out of CON compliance. If the intent of this section was to try to make sure the Minimum Design Standards are complied with, the Public Health Code (Part 201) more than adequately addresses this due to the fact that no facility can obtain a license without compliance. We ask, "How can someone certify something in advance of the time it is required to be submitted and approve?" The most one can certify is that they will "attempt to meet the standards at the time of submission". In any event, prior to opening a facility's "doors" to residents the design standards are meet or else the facility would not be able to obtain a license. Thus, we request the deletion of this section as it does not belong in the CON standards and is already provided for at the appropriate time during a construction project under the Public Health Code.

Plan of Correction Requirements-

In Section 6, , line 341, (Section 6, I, C, page 7) , Section Seven, line 521-524 (Section 7, II, B page 11, Section 8, lines 577-580 (Section 8, 1,E, page 12), Section 8, lines 626-629, (Section 8, 2, E page 13), Section 9, lines 726-729 (Section 9,1, E page 15) Section 9, lines 786-789, (Section 9,3, C, page 16) the Standards would require both the submission **and approval** of a plan of correction (POC) for survey deficiencies at the time a CON application is made. Unfortunately, the realities of the survey process do not fit with this requirement as currently worded. Often there is a lag time between a survey and a notice of deficiency, as well as a lag time in the processing of a survey and approval of a POC. Also, there could be the situation in which an applicant is surveyed close to the time of the intended submission of a CON application (the batch date) whereby a potential applicant would be prohibited from making a CON application merely by the timing of a survey. We therefore support a wording change such that the plan of correction submission only stand as a requirement if the POC is actually due prior

to the date of the CON application; and further, request that the requirement for **approval** of a POC be struck from the Standards.

Single Occupancy Rooms:

In Section 6, lines 454-457, (Section 6, 2 , C page 9) and Section 8, lines 656-662 (Section 8, 3, B, page 13) each contain a requirement for 80% of the beds to be in single occupancy resident rooms. It is important to note that the original pilot new design projects percentages were based on the numbers of the **rooms** that were single occupancy not the number of the **beds** in the facility. This switch from "rooms" to "beds" is not an insignificant change and results in a far stricter requirement and much more expensive project. In addition, it could result in less projects being undertaken on the part of providers to incorporate the new design standards. It is our understanding that the State of Michigan wishes to encourage the proliferation of more facilities either renovating or constructing using the new design standards. We, therefore request that the wording be switched back to "rooms" to reflect the requirements of the original new design standards. This change would also bring consistency with the comparative review criteria in Section10, line 886 (Section 10, 8, page 19) that correctly uses the criteria based upon the number of rooms that are single occupancy and not the number of beds.

In addition, we strongly assert that the 80% requirement in both Section 6, 2 (C), and the comparative review criteria in Section 10, line 886 (Section 10, 8, page 19) would similarly increase the cost of construction such that the facilities with a large Medicaid population would be unable to implement design and renovation or replacement changes. The reality of the amount of reimbursement, as provided for under the Medicaid program, would not allow a facility, who has made the commitment to serve the Medicaid population, to entertain facility construction projects were the level of single occupancy rooms to remain at an 80% percent level. We, therefore request that the percentage be brought down to 50% of the rooms. This percentage will more readily allow **all** facilities regardless of the payor mix to make needed improvements and changes to a facility for the benefit of its residents.

Relocation Restriction Limited to Seven Years:

Further in Section Seven, Line 504-5, (Section 7, I, D, page 10) a relocation of beds could only be accomplished once in seven years. This provision limits the frequency in which beds can be relocated. Under the Michigan Medicaid program, beds are permitted to be taken out of service for a period not to exceed two years without being impacted by a minimum occupancy policy. We feel that the Medicaid standard of two years more closely aligns with the reality of the market and the ability of facilities to predict occupancy and future financial constraints. Tendercare asserts that the seven year limitation for relocation is unduly restrictive and would require facilities to forecast population changes and other factors seven years into the future. Tendercare supports and recommends that the seven year limitation be reduced to a two year limitation.

Comparative Review Standards:

Section 10 sets out the Comparative review standards. It would appear that as currently written, the comparative review criteria sets up a system that favors those

providers/applicants who are already operating facilities over a newly created facility or legal entity. As a result, new development of facilities by way of new construction would be materially disadvantaged under the proposed criteria. Under the proposed criteria, it will be easier to prevail on an application for expansion over one for a new building. The FIDS program was an effort to stimulate innovative design initiatives and culture-change. Many times such changes are not feasible within an existing facility footprint. Thus, if the State of Michigan truly wishes to foster such innovation, it is important to recognize that at times new construction, by operators who have the capital to finance such projects is needed. Therefore, it makes little sense to implement criteria that squelches the chances of new and potentially innovative facilities.

Therefore, we recommend that, in Section 10, lines 800-850 (Section 10, Part 2 and 3, page 16-17) the language which awards points based upon a 12 month facility history be altered to allow for points to be awarded for a **commitment** to participate in Medicaid. Such an addition will provide for an even assessment between an existing facility applicant and a new facility applicant.

Section 10, Line 884-886 (Section 10, Part 8, page 19) in the Comparative Review Criteria makes reference to facility design that would include a space designated as "adjacent private changing room". There does not appear to be any defining criteria as to what this space actually must be. Clarification as to how one would meet the definition of an adjacent private room would be helpful. As this criteria is part of an assessment of a central shower configuration, we request that the language be changed such that it read "adjacent private changing **area**".

Lastly, and of significance Tendercare's concern about a set of quality standards that will be implemented in such a way that the survey criteria in the Quality Measures get effectively applied retroactively. This concern is even heightened by the stringent criteria that look at Level D and above citations on the scope and severity grid. Most providers when receiving survey citations make a calculated cost benefit analysis as to whether or not to contest a citation. It is clearly and very possible that the cost/ benefit analysis equation under the proposed quality measures would have been different than without those measures. This would be particularly true of citations at a level D or above on the scope and severity grid. Therefore, Tendercare respectfully, submits that some form of progressive introduction of the standards be introduced upon the effective date of the Standards. Such an approach would be consistent with a "slow and incremental" change approach that Tendercare favors and advocates.

Thus we would request for consideration, that the quality history is assessed from the effective date of the Standards, going forward, such that eventually look-back of quality history data would be begin to be assessed, though not immediately upon implementation. However, the actual point that the review approximates a look-back of data history is then phased in. In the event that this phase-in is not accepted as an approach, then the only alternative and fair approach would be to alter the "Level D and above" citation criteria to a "Level E and above" criteria. This would have the effect of

mitigating some of the impact of a retroactive look back approach in the implementation of the quality measures.

Thank you for your patience and time in allowing us the opportunity to provide our comments regarding these standards. As we move forward in the years to come we hope that everyone involved in the development and implementation of these new Standards will be able to look at the changes they have brought about and see effects that are positive for those who entrust us with their health care needs.

Respectfully Submitted,
Jonathan Neagle
Area Vice President
Tendercare (Michigan), Inc.
Extendicare Health Services, Inc.

TESTIMONY ON PROPOSED CON STANDARDS FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS
FOR PUBLIC HEARING ON FEBRUARY 6, 2008

Submitted by HCR ManorCare, Inc.

HCR ManorCare, Inc., through its subsidiaries and affiliates ("HCR ManorCare"), operates more than 275 licensed nursing homes nationwide, including twenty-eight nursing home facilities in Michigan. As one of the largest long-term care providers in Michigan, we appreciate this opportunity to provide public comment on proposed revisions to the Certificate of Need ("CON") Review Standards for Nursing Home and Hospital Long-Term Care Unit Beds.

The CON Commission took proposed action to approve revised CON Standards at its meeting on December 17, 2007. We commend the Commission for taking action at its December meeting to require the Michigan Department of Community Health ("Department") to hold workgroup meetings prior to today's public hearing given there were widespread and material concerns from the long-term care provider community as to the proposed Standards. HCR ManorCare participated in those workgroup meetings and had an opportunity, along with other providers, to express our concerns as to many of the proposed revisions.

HCR ManorCare supports the delivery of quality services by all nursing homes. Although HCR ManorCare continues to have reservations as to whether CON Standards based on survey outcomes will result in the most qualified CON applicants, the "compromise proposal" on the quality measures developed by the workgroup represents a substantial improvement to the proposed Standards approved by the Commission at the December 2007 meeting. Thus, despite some ongoing concerns with this approach, HCR ManorCare supports the compromise proposal, with the assumption that the CON Commission will re-visit the Standards if this approach has unintended consequences or irrational outcomes. In our experience, good public policy is developed through positive incremental change. We are pleased that the Compromise Proposal represents a more incremental approach.

Unfortunately though, the Commission's work on these Standards is not complete. Because the proposed quality measures monopolized much of the SAC's time, regrettably, many other critical issues in the proposed Standards received little attention. Some of these issues will implement potentially harmful policies or materially and adversely impact the fairness of the Michigan CON process. Also, in many instances, these additional issues may prevent the most

qualified applicant from obtaining additional nursing home beds. These issues *must* be **addressed before the Standards are finalized.** These concerns are briefly outlined below. Please note that the references below as to "Line Numbers" correspond to the amended version of the proposed Standards posted by the Department for today's public hearing.

- Comparative Review Criteria (Lines 791-920). The draft comparative review criteria/scoring materially favor an existing applicant/operator over a new legal entity. We are not aware of any rational basis for this approach as it is a common legal structure in the health care arena to establish a separate business entity for each licensed facility. Unless corrected, these criteria will favor expansion of existing buildings and materially disfavor development/construction of new facilities. Over the past 10 years, the trend in nursing home construction has been away from "mega-buildings" and toward more residential buildings with 100-125 beds, such as the new design model projects. In addition, the construction of new nursing homes improves the infrastructure of the Michigan nursing home inventory. We are unclear why the Commission or the Department would support language that will restore the trend toward super-sized nursing homes, thereby discouraging construction of new and innovative nursing home designs. ***See Example 1 in the attached Addendum.***
- Approved Plan of Correction (Lines 341-344; 521-524; 577-580; 726-729; 786-789). Language in the CON Standards would require an applicant to demonstrate that it has a Department-approved plan of correction ("POC") for ANY cited deficiencies (regardless of scope and severity level) *at the time the CON application is filed.* This criterion ignores the normal compliance schedule and framework for licensed and certified nursing homes. In many instances, a plan of correction *may not even be due* prior to the CON filing date. Alternatively, the provider could submit the plan of correction early, only to have a delay in processing of the plan of correction by the Department preclude the applicant from being able to submit a CON application. We also note that new design model projects appear to be exempt from this general quality assurance requirement although we do not see any compelling policy reason for that decision. ***See Example 2 in the attached Addendum.***

- Certification as to Compliance with Minimum Design Standards (Lines 336-340; 572-576; 621-625). We see no reason for an applicant to certify that the Minimum Design Standards for Health Facilities (health facility construction/construction permit requirements) will be met *when the architectural plans are submitted for review and approval by the Department.* Clearly, the Minimum Design Standards must be met for a CON-approved project to obtain a health facility construction permit. However, frequently, the plans are not 100% compliant with the Department's interpretation and application of the Minimum Design Standards upon initial submission of the architectural plans, even when prepared by an experienced and qualified architect. Rather the health facility construction plan approval process involves some "give and take" with the Department before full compliance is achieved. There is no need to tie this requirement into the CON Standards as it is already legally required under Part 201 of the Public Health Code. Alternatively, if the CON Commission retains this requirement, the Standards should simply say that the CON approved applicant will demonstrate compliance with the Minimum Design Standards prior to initiating construction – not upon initial submission of the blueprints. ***See Example 3 in the attached Addendum.***
- New Design Model Language (Lines 454-457; 656-662). It is our understanding that the intent of the SAC was to move the language from the Addendum for the Pilot Program for New Design Models to the body of the Standards. In this process, the requirement as to private accommodations was modified from 80% private *rooms* to 80% private *beds*. This is a materially more difficult and burdensome standard that we believe will discourage providers from constructing new design model facilities. ***See Example 4 in the attached Addendum.*** Testimony at the SAC suggested that construction costs for a new design model nursing home may run up from $60,000 - $80,000 more per bed than traditional nursing home construction. This is due in part to the requirement for private rooms. Given the CON Commission, by statute, must consider cost, as well as quality and access, we believe that the 80% private bed requirement is unduly restrictive, cost prohibitive in many instances, and likely to discourage construction of new design model facilities.
- Relocation of Nursing Home Beds (See Lines 489-525). HCR ManorCare supports the addition of language to allow relocation of some nursing home beds from one existing

facility to another existing facility within the same planning area. In our view, relocation may help even out small problems with the allocation of nursing home beds within a planning area. However, we suggest a cap on the number of beds that can be relocated, in addition to the limit on relocation of up to 50% of a facility's unoccupied beds. If a maximum of 40 existing beds (i.e., no more than two 20-bed units) could be relocated, this would provide some ability to even out allocation of nursing home beds in the planning area, but not allow for establishment of entire new nursing home facilities outside of the bed need and comparative review process.

- Implementation of the New Quality Measures. The new quality measures clearly constitute a significant departure from the existing CON Standards and signal a new approach for awarding CON approvals in Michigan. However, because this system is materially so innovative, it would be reasonable to implement the new criteria on a "rolling" basis as follows: Assume the Standards become effective May 1, 2008. If a provider filed a CON application on the June 1 batch date for comparative review applications, quality history from May 1, 2008 through June 1, 2008 could be reviewed. If they filed an application on the June 1, 2009 batch date, quality information from May 1, 2008 through June 1, 2009 would be considered. Eventually, there would be three-year look-back but not until three years after the effective date. In the interim, the Standards would be effective but quality history would only count from the May 1, 2008 date forward. This approach would give providers an opportunity to become familiar with the new requirements, reduce the likelihood of litigation in comparative review applications, and potentially ease the administrative burden for the Department in implementing these new Standards. We expect that CON forms will need to be revised to address these criteria and that a number of questions will arise once the Department starts receiving CON applications under the new Standards. This approach would allow for the gradual transition from the existing system to the new requirements.

ADDENDUM A

Specific Examples

1. Example 1: Comparative Review Criteria (Lines 791-920).

The following example compares the scoring under the proposed comparative review criteria for a new legal entity versus an existing entity. Applicant A (a new legal entity) could be a new company formed as a subsidiary of a high quality nursing home operator that is seeking to construct a new 100 bed nursing home. Applicant B (an existing entity) could be an existing operator with a mediocre quality history seeking to add beds to an existing nursing home.

Comparative Review Criterion in Section 10	**Applicant A: New Legal Entity Proposing New 100 Bed Nursing Home**	**Applicant B: Existing Operator Seeking to Add 100 Beds to Existing Building with 150 Beds**
Section 10(2)(a) – Percentage of Medicaid Patient Days Based on Most Recent 12 Months of Operation	0 points awarded because new entity will not have any operating history.	Potential for 12 points if maximum number of Medicaid patient days
Section 10(2)(b) – Percentage of beds certified for Medicaid participation in Most Recent 12 Months of Operation	0 points awarded because new entity will not have any operating history.	Potential for 9 points if maximum number of Medicaid certified beds
Section 10(3) – Medicare certification in Most Recent 12 Months of Operation	0 points awarded because new entity will not have any operating history.	Potential for 2 points if maximum number of Medicare certified beds.
Section 10(4) – Points Deducted for Revocation of License (4), Medicare Certification (4), or Medicaid Certification (4)	0 points could be deducted because new entity will not have any operating history.	Although theoretically 12 points could be deducted, no entity that has had a license, Medicare or Medicaid certification deducted is likely to be a CON applicant.
Section 10(5) – Existing or Proposed Culture Change Model	Potential for 9 points if new entity proposes to have culture change model	Same as Applicant A
Section 10(6) – Percentage of cash contributed to proposed project	Potential for 10 points if 20% or more cash to fund proposed project	Same as Applicant A
Section 10(7) – Sprinklers in new or existing facility	Potential for 6 points if sprinklers in proposed project	Same as Applicant A
Section 10(8) – 80% private rooms and/or toilets and	Potential for 6 points if 80% private rooms in proposed	Same as Applicant A

showers	project with private toilet and sink and private showers or centralized showers with private changing area	
Tally of Total Possible Points under Most Favorable Scoring	(2)(a): 0 (2)(b): 0 (3): 0 (4): 0 deducted (5): 9 (6): 10 (7): 6 (8): 6 Total: 31	(2)(a): 12 (2)(b): 9 (3): 2 (4): 0 deducted (5): 9 (6): 10 (7): 6 (8): 6 Total: 54

2. **Example 2: Approved Plan of Correction (Lines 341-344; 521-524; 577-580; 726-729; 786-789).**

Both Applicant A and Applicant B determine in February 2008 that nursing home beds are available in the planning area. Each entity begins preparing a CON application for a new 100-bed facility for submission on the next CON "batch date" of June 1, 2008.

Applicant A has an excellent quality record and very good survey outcomes, however, its normal annual survey window is late April – early May 2009. On May 10, 2008, State surveyors arrive at Applicant A for the annual survey. Surveyors find one B level deficiency (pattern of practice with no actual harm but potential for minimum harm). Applicant A does not receive the statement of deficiencies from MDCH until May 30, 2008. Although its plan of correction is not due until June 9, 2008, Applicant A quickly prepares and submits a plan of correction. However, MDCH does not have time to approve the plan of correction prior June 4, 2008. Applicant A is not a qualifying CON applicant and is precluded from submitting its CON application even though MDCH accepts its plan of correction and the low-level deficiency is immediately corrected.

Applicant B has a spotty quality history and had a particularly poor survey in January 2008. However, Applicant B had ample time to submit a plan of correction for cited deficiencies prior to the June 1, 2008 batch date. Applicant B does not propose any culture change or private rooms as part of its project and would have been readily outscored by Applicant A in a comparative review. However, because Applicant A is precluded from filing, Applicant B is awarded the beds as the only applicant in the comparative review batch.

3. **Example 3: Certification as to Compliance with Minimum Design Standards (Lines 336-340; 572-576; 621-625).**

Applicant A is awarded a CON for a new 100-bed nursing home facility. Consistent with its existing legal obligations under Part 201 of the Code, the architect retained by Applicant A

prepares and submits blueprints to the Department of Community Health, Health Facility Engineering Section ("HFES"). HFES determines that, upon submission, the plans do not fully satisfy the Minimum Design Standards and that a few minor modifications are required based on HFES' interpretation of the Standards. The architect re-submits the plans with the corrections and the plans are approved.

Is Applicant A's CON invalid because the blueprints did not initially satisfy the Minimum Design Standards as required by the Proposed Standards?

4. <u>Example 4: New Design Model Language (Lines 454-457; 656-662)</u>.

It is our understanding that the intent of the SAC was to move the language from the Addendum for the Pilot Program for New Design Models to the body of the Standards. However, in this process, the requirement as to private accommodations was modified from 80% private *rooms* to 80% private *beds*. This is a materially more difficult and burdensome standard that will discourage providers from constructing new design model facilities as demonstrated by the following example for a 100-bed new model design facility with 68 private rooms and 16 semi-private rooms.

- **If 80% Private Rooms (original language) applies, calculate private rooms as**:

  68 private rooms ÷ 84 total rooms = 80.9% which satisfies 80% private room test

- **If 80% Private Beds (new language) applies, calculate private beds as**:

  68 private beds ÷ 100 total beds = 68% which does not satisfy 80% private bed test. To comply, the number of private beds, i.e., private rooms would need to be increased from 68 private rooms to 80 private rooms. There is a material cost differential associated with this alternative that will likely discourage new design model facilities.

MICHIGAN LONG TERM CARE OMBUDSMAN

Testimony of Sarah Slocum, State Long Term Care Ombudsman, to the Michigan Certificate of Need Commission on Proposed Nursing Home Standards.

February 6, 2008

Thank you for the opportunity to comment on these proposed Certificate of Need Standards (CON) for Nursing Homes and Hospital Long Term Care Units. As a member of both the Nursing Home Standards Advisory Committee (NHSAC), and the workgroup assembled in January 2008 to review the Quality standards, I feel that this effort has created a true consensus document which you have before you today.

I deeply appreciate the CON Commission's action in December 2007, accepting the majority of the recommendations from the NHSAC. I continue to support the implementation of the proposed standards which were accepted in December.

I also strongly support CON Commission approval and Department implementation of the revised Quality standards as presented by the workgroup. Several changes were made to deal with concerns from various interested parties including:

- Out-of-state providers' who also have a significant Michigan presence were relieved of the burden of producing lengthy reports of their track records in other states.
- Simplification of Quality standards by removing two of the less serious infractions from the list of incidents that restrict CON activity (repeat harm citations and repeat staffing citations).
- Adjusting and clarifying the time period under review for survey-based measures to make the measure more "real-time".

I am truly impressed with the level of cooperation and sincere dedication to problem solving shown by provider representatives and consumer representatives in the Quality Standards Workgroup. I thank all who participated, and hope for swift adoption of this Consensus Proposal on Quality by the CON Commission.

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