AA Testimony

1.+Name: Judy Kettenstock
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5.+Standard: AA
6.+Testimony: I am writing regarding the CON standards for Air Ambulance in the State of Michigan. I believe the standards as they are set are realistic accurate numbers to determine if an area needs a new air medical program or additional helicopters added to an existing program. I believe the standards should be left as they are.

1.+Name: Meg Tipton
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5.+Standard: AA
6.+Testimony:
January 12, 2007

Norma Hagenow, 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 Ms. Hagenow,

This letter is written to offer the comments of Spectrum Health on suggested changes to the CON Review Standards for Air Ambulance Services. We suggest that the CON Review Standards should address the following distinct areas for Air Ambulance.

Definitions:
"The current standards define "air medical personnel" to include at least 2 members, one of which shall be a paramedic licensed in Michigan.
Spectrum Health believes that the current language may be too restrictive and may contribute to unnecessary duplication of costly medical personnel. We propose that either a physician who is specially trained in the area of emergency medicine or a paramedic licensed in the State of Michigan be included in the CON definition. This proposed change would continue to require air ambulance services to adequately meet the needs of providing excellent patient care in an emergent situation while efficiently meeting their staffing needs.

Addition of a Twelve (12) Hour Aircraft:
When adding air ambulance capacity, it is common practice among air medical transport companies to add additional aircraft time incrementally. Since most air ambulance companies currently include a back-up aircraft, and since most companies schedule staff for 12-hour shift lengths, it would be an easy transition to go from one (1) aircraft to 1.5 aircraft. An improvement in the CON Review Standards would make allowance for a "Twelve (12) hour aircraft," which would be the second aircraft operated by the service that would be available for missions twelve (12) hours per day. This means that one aircraft would be available 24 hours/day and the second aircraft would be available twelve (12) hours per day. Spectrum Health proposes that the Air Ambulance Service CON Standards be revised to allow for a second aircraft to be used twelve (12) hours per day.

Expansion of Air Ambulance Services:
In Sec. 4 (b) of the Air Ambulance Standards, an applicant proposing to expand an air ambulance service must both achieve a minimum volume of patient transports and project an increase in future patient transports. For example, an air ambulance service with 1 air ambulance must

perform at least 600 transports annually and project that at least 800 patients transports (600 x 1 + 200 = 800) will be made in months 7 through 18 after beginning operation of the additional air ambulance. This requirement may be overly restrictive. In other CON review standards, a fixed volume requirement is specified without a projected increase. For example, in the MRI Standards, an existing service achieving 11,000 adjusted MRI procedures per machine qualifies for an additional unit. A consistent requirement for air ambulance should be applied.

Spectrum Health proposes that language relating to applicants proposing to expand an air ambulance be changed to require an actual volume of 600 patient transports, without any volume projections.

Replacement of an aircraft:
Spectrum Health would like to further recommend the modification of the requirement for approval for applicants proposing to replace an air ambulance in Section 5 (b) of the air ambulance CON standards. The current standard language is confusing. As currently stated, the Standards appear to require an applicant proposing to replace one of two (2) aircraft to have performed at least 1,400 (600x2 + 200) patient transports, which is also the current requirement for adding a third aircraft. Spectrum Health proposes to eliminate this cross-reference to Section 4 (b) of the air ambulance CON standards and to clearly specify the volume requirements for replacement of an aircraft which should be considerably less than 1400 patient transports for two (2) aircraft.

Additionally, within the Air Ambulance CON standards for the replacement of an air ambulance it appears that there is a duplication of requirements. As currently stated in Section 5 (d), an applicant proposing to replace an air ambulance must meet the project delivery requirements in Section 8. Spectrum Health proposes that the Air Ambulance CON standard, Section 5 (d) be revised to require an applicant to either demonstrate accreditation by the Commission on the Accreditation of Air Medical Services (CAAMS) or address all the project delivery requirements set forth in Section 8. We suggest that it be considered prima facie evidence for Section 8 if an applicant submits documentation of current CAAMS accreditation.

Spectrum Health appreciates the opportunity to share our views on needed improvements to the CON Review Standards for Air Ambulance services.
Sincerely,

Meg Tipton
Strategic Regulatory Associate

CT Testimony

1.+Name: Mike Abney
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5.+Standard: CT
6.+Testimony: Introduction

This recommends that an alternative standard of CT equivalents be established for point of care CT scanners. Point of care CT scans are those administered at the patient's location or bedside rather than having the patient come to the scanner. My company produces the CereTom, a portable CT scanner that is able to create high quality images of the head and neck in adults. I define portable as being able to move within a facility. I use the term "portable" rather than "mobile" so that no confusion is created about the machine moving between facilities. The machine moves within one facility to the patients' point of care (patient bedside in the ICU, ER, OR etc). On our website, we use the term "mobile" differently than as defined in the CON Review Standards for CT Scanner Services, Section 2, paragraph x. Our website with the CereTom can be seen here: http://www.neurologica.com/Products.aspx .

Why the CereTom is important to the state of Michigan

Access
The CereTom offers a service that other CT scanners cannot replicate. Another 16 or 64 slice CT scanner offers the same scans and services that exist currently. The CereTom provides CT access to patients who have been underserved by traditional CT scanners. In an ICU setting, the CereTom is able to scan the patients who have been too sick or too risky to move to radiology or who are simply too large to scan on other machines. In an ER setting, the CereTom can improve the time to scan for stroke and traumatic brain injury (TBI) patients. In an OR setting, the CereTom can scan prior to closing a patient. In a pediatric ICU setting, the CereTom can do whole body scans of babies attached to other machines such as ECMO units.

The CereTom targets the two most disabling events and the third and fourth leading causes of death in adults: stroke and TBI. Both of these events are one to two week emergencies that require multiple scans of the patient's head. During that time patients go through a rollercoaster, struggling with brain swelling, blood clots and brain damage. Having a CereTom available for these patients helps shorten hospital stays and improve their outcomes. As required in Section 13, paragraph B, sub paragraph (vi) a CT scanner facility must be able to handle emergencies that occur in the CT unit. We make the case that those patients in an ICU with head injuries are best scanned in the ICU in the bed they are already in. The ICU is the place best equipped to handle emergencies with these patients and prevents any problems in transit. In addition to the enhanced level of care given to the patient being scanned, the other patients in the ICU have greater access to care as well. When an ICU patient with head injuries is transported, a nurse and respiratory therapist (RT) travel with the patient. This removes valuable staff from the ICU. Nurses who were caring for one or two patients are now responsible for two to three. The RT who was responsible for six to ten patients is now responsible for 11 to 19. When the patient reaches radiology, all other patients for that machine must wait until that patient's scan is complete which limits their access. It usually takes an hour to an hour and half to prepare an ICU patient for transport to radiology, get scanned and return to their room. In contrast, the time required from when a CereTom arrives at a patient room to completion of a scan is usually about 20 minutes and everyone stays on the ICU floor. Stroke and TBI are not fair in who they impact. There is a socio-economic disparity in their incidence. In addition to that, approximately 20% of stroke patients are obese. The size of these patients can prevent their being scanned elsewhere. Stroke is tied to heart disease as well. Cardiac patients often have problems with blood clots being sent to the brain or experience a lack of oxygen to the brain. Both problems require head scans of critically ill patients. The CereTom was designed to provide greater access for all of these patients.

Quality

The CereTom is an 8 slice CT scanner. Because it was designed for use on the head and neck, two parts of the body that do not move during the scan, it is able to produce images comparable in quality to 64 slice machines. I can provide copies of images or references. Currently, we are in many of the leading neuro hospitals in the country: Cleveland Clinic, Columbia Presbyterian, Massachusetts General Hospital, Ben Taub, UCLA Medical Center, University Hospital in Cincinnati, Barnes Jewish Christian etc. Typically, the units are housed on an ICU floor and move to the patients on that unit. We have placed 30 CereToms over the past year and anticipate placing another 80 to 100 this year. The technology is rapidly becoming the standard of care for neuro ICU patients. The clinicians, Neurologists, Neurosurgeons, Neuro-Intensivists, Radiologists, etc. understand how the technology improves both patient and provider care. Some of those clinicians are in Michigan and want to add the CereTom to their facilities. They may submit letters in support of an alternative standard for CT scans administered at the patient's point of care.

Another component of quality is dependability. The machine was designed to be durable. Included in the service plan is preventative maintenance three times a year, all software upgrades, replacement of the tube if it fails, all consumables (belts, brushes and batteries), a local service technician and telephone support. We have never had a tube fail.

Cost

The CereTom is tremendously less expensive than new, full body CT scanners. Depending on the options selected, most CereToms are between $330,000 and $370,000. The basic service plan outlined in the 2nd paragraph under Access is $35,000 per year. The first twelve months of service are included with the CereTom. The scans completed by the CereTom are reimbursable under existing CT scan codes by Medicare, Medicaid and insurance companies.

There are other cost benefits of using the CereTom. The scanners in radiology usually see an increase in scans performed once the ICU patients are not brought to radiology. There is a decrease in cost spent in preparing and transporting patients to radiology. ICU and hospitals stays are shortened because scan information is available for patients who may not have been able to get scanned as needed. This leads to better outcomes and a higher likelihood of returning the patient back to work.

Proposed Alternative Operating Level Standards of CT Equivalents for Point of Care CT Scans

I am basing my proposed alternative standards on the numbers we are seeing in the facilities that are currently using the CereTom. I am using these numbers as my Documentation of Projections, Section 16 of the CON Review Standards. From there I will present two potential alternative standards for point of care CT scanners.

We are seeing between 4 to 20 patients per day scanned in facilities with the CereTom Monday through Friday. Some facilities do not scan with the CereTom on weekends or holidays. The standard number of scans that most places expect on a daily basis during the work week is between 7 to 10. For the purposes of this analysis I will use 6 scans per day, 7 days a week for the entire year. This is an approximation. The type of facility, patient population, the location of the CereTom in the facility, weekends, holidays, etc all play a part in the number of scans conducted on a daily basis.

6 scans per days x 7 days per week x 52 weeks per year = 2184 scans per year

Based on this, one potential alternative standard for point of care CT scanners would be to assign all point of care CT scans a conversion factor of one and make the annual operating level of CT equivalents 2000. There is some precedence for using a lower number of CT equivalents for different technologies. Mobile units are currently at 3500 CT equivalents annually.

A second potential alternative standard for point of care CT scanners would be to adjust the conversion factors:

Category/Conversion Factor
Point of Care Head Scans w/o Contrast
3.5
Point of Care Head Scans with Contrast
3.75
Point of Care Head Scans w/o & w Contrast
5.25
Point of Care Pediatric Body Scans w/o Contrast
5.0
Point of Care Pediatric Body Scans with Contrast
6.0
Point of Care Pediatric Body Scans w/o & w Contrast
8.25

Using these conversion factors would allow the CereTom to use the 7500 CT equivalents per year standard of other fixed CT scanners.

Conclusions
CT scanner technology has advanced dramatically since the current Review Standards for CT were written. Based on current CT standards, it is extremely unlikely that a high quality, portable CT scanner offering increased access and decreased costs could be made available in Michigan. Our CereTom offers the opportunity to improve patient care and is rapidly becoming the standard of care for stroke and TBI patients. While improving patient care, it makes the jobs of health care providers easier. Clinicians understand how to implement the technology and are eager to do so in Michigan. The quality of images produced is comparable to any full body scanners on the market. The services provided by the CereTom are reimbursable under existing codes.

Based on everything presented in this written testimony, I urge the committee to adopt an alternative operating level standard for point of care CT Scanners. The brain defines who we are. Failing to preserve the brain when there is a stroke or TBI has a much more dramatic impact on quality of life than nearly any other injury. The CereTom is vital for the care of patients with those injuries.

I look forward to working with The Commission to bring this technology to the good people of Michigan. Please contact me with any questions or to arrange for any follow up requirements.

Mike Abney,
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6.+Testimony: Should Michigan CON apply to Specialty CT Scanners?

Michigan Patients May be Subjected to Excessive Radiation Exposure

Michigan Should Carve Out Exception to CON for Inexpensive, Low Radiation Dose Specialty CT Scanners CT is the gold standard of care for diagnosing sinus and ear problems. For proper diagnosis, physicians such as Ear, Nose and Throat surgeons and Allergists, routinely order sinus and ear CT scans for their patients. They can send their patients offsite to a hospital or imaging center for a sinus/ear CT scan performed on a conventional, full-body CT scanner, or they can perform a low radiation dose, 40 second sinus/ear CT scan during the patient's office examination with a small, upright, sinus/ear CT scanner called "MiniCAT™."
MiniCAT™ is meant to be used directly at the patient's point of care to give physicians instant access to the information they need to properly diagnose their patients so they can start their

treatment right away and get faster relief from their symptoms. Physicians who use MiniCAT™, in rural and urban offices alike, can provide their patients with the added benefit of having their scans read and radiology reports created by highly sub-specialized Neuroradiologists/Head and Neck Radiologists via an online teleradiology program. Sinus and ear patients who undergo CT scans on full-body scanners must make multiple appointments between their physician's office and a hospital or imaging center before they can be diagnosed and start their treatment—a process that can take days or weeks. More importantly, however, they will also receive from 7-28x greater radiation dose for a sinus/ear CT scan performed on a conventional, full-body CT scanner than for the same CT scan performed on MiniCAT™. As it stands now, the Michigan CON effectively prevents Michigan physicians from purchasing specialty diagnostic CT scanners, such as the MiniCAT™ low radiation dose sinus/ear CT scanner, and their patients are forced to go to hospitals or imaging centers for CT scans performed on full-body CT scanners—this causes delays in diagnosis and treatment, increased costs for multiple office/hospital exams, and subjects Michigan patients to higher, unnecessary radiation doses.

Give Physicians the Diagnostic Tools They Need and Protect Michigan Patients from Excessive Radiation Dose Before the advent of CT scanners as we know them now, ENT physicians and Allergists used 2D x-ray machines in their offices to diagnose their patients during their exams. The introduction of CT 3D x-ray technology about 25 years ago gave physicians an unprecedented, non-invasive means to detect disease and injury in great scope and detail. But because conventional CT scanners are massive, expensive, and complex to operate, they were consigned mainly for use in hospitals and imaging centers. ENT physicians and Allergists then abandoned their 2D x-ray machines and started sending their patients to hospitals for CT scans. Every year, the major conventional CT scanning companies, such as GE, Siemens, Philips, and others, develop increasingly better, faster, and more expensive full-body CT scanners that are now so sophisticated that they create incredibly precise images of the beating heart and detailed views of intricate brain tissue—all of which requires higher radiation doses than necessary for creating diagnostic scans of the sinuses and ears. ENT physicians and Allergists do not need these sophisticated features, and patients do not need the excessive radiation dose that goes along with them. The recent development of small, specialized CT scanners, like MiniCAT™, brings back a crucial diagnostic tool to the patient's point of care. Allowing Michigan physicians to offer their patients onsite, instant diagnosis with specialized, low radiation dose CT scanners frees up the expensive, full-body CT scanners so they can be used for the sophisticated imaging tasks they were designed for. This results in a better utilization of State resources.

Possible Solutions:
- Exempt specialty CT scanners from the Michigan CT CON
- Create price threshold for applicability of Michigan CT CON (i.e. greater than $1M)
- Create radiation dose threshold for applicability of Michigan CT CON (CT scanners that generate radiation dose higher than "X" require CON approval)

Attachments:
MiniCAT™ specifications
MiniCAT™ radiation dose page

1.+Name: Robert Meeker
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4.+Email: robert.meeker@spectrum-health.org
5.+Standard: CT
6.+Testimony: This is Spectrum Health's formal testimony about the CON Review Standards for Computed Tomography (CT) Scanner Services which went into effect December 27, 2006. We appreciate the opportunity to comment on these Standards. In general, the CT Standards have served well in allocating the appropriate number of CT units across the state of Michigan. The substantial portions of the standards were developed more than five (5) years ago and include volume requirements for initiation and expansion of CT services which are both reasonable and appropriate. However, there are some particular provisions of the Standards which need to be reviewed and updated. The specific areas needing revision include the following: clarification of the requirements for relocation, revised definition of replacement, specific acknowledgement of

the imaging requirements for pediatric patients, and allowance for new CT technology. Each of these areas is addressed separately below.

Relocation of an existing CT Scanner Service.

There are several concerns with the existing requirements for relocation of an existing CT service. Our primary concern is the requirement that relocation applies to all of the units in an existing CT service, rather than to only one or some of its CT units. Recent changes approved to the MRI Standards specifically allow the relocation of individual units of an MRI service. A similar modification should be made to the CT Standards. An additional requirement of the relocation section (#7) of the Standards is that the unit to be relocated must have performed 7,500 CT equivalents in the most recent year. One likely reason to relocate a CT unit or service is because it may be operating below an optimal volume level due to a disadvantageous location. The Standards should not prohibit the ability of a CT provider to relocate an underperforming CT unit to a better location. The volume requirement for relocation should either be eliminated or substantially reduced. Finally, the existing Standards require a CT service proposed to be relocated to have been in operation for at least 36 months. While it makes sense that a CT scanner to be relocated should be established at its current location, 36 months is an excessive length of time and should be reduced. A requirement of 24 months would be more appropriate.

Definition of Replacement of an existing CT Scanner.

Under the current definition of "Replace/Upgrade a CT Scanner," virtually any change to the equipment, including routine maintenance, would require CON approval. Again using the MRI Standards as an example, the definition of replacement includes a specific level of expenditure. For MRI, replacement entails spending more than $750,000 on upgrades to the equipment over a 24-month period. CT technology is less costly than MRI; an expenditure of less than $400,000 over two (2) years would be an appropriate level to be exempt from CON review as a replacement.

Considerations for Pediatric Patients.

Several of the CON Review Standards include weights or allowances for the needs of pediatric patients. Indeed, the Standards for MRI and PET provide separate requirements for dedicated pediatric units. The CT requirements for children are not so significant as to indicate the need for dedicated pediatric CT units; however, many of the same pediatric considerations for MRI – including sedation, special needs, etc. – also apply to CT scanning. Therefore, as a simple mechanism to account for the special needs of pediatric patients, Spectrum Health suggests that a weight of .25 be added to each procedure involving a patient <15 years old.

Special Use CT Scanners.

During the last year, the CON Commission developed separate CON requirements for "dental CT scanners." Other special use CT devices, which are available now or may be in the near future, may require unique CON standards. One example now available is a Xenon CT Scanner, which is used in Level I Trauma Centers for seriously brain-injured patients. Such specialized units would never be expected to achieve annual utilization approaching 7,500 CT equivalents per year. Lower volume requirements should be considered for such special use machines, under specific circumstances. However, in developing such specific criteria, care must be exercised to not allow proliferation of "special use" CT machines with very low volume requirements.

Many of the issues mentioned in this letter are primarily technical in nature and may be able to be resolved using an informal process. However, other concerns may necessitate establishment of a Standards Advisory Committee to determine appropriate revisions of the CT Standards. Spectrum Health appreciates the opportunity to comment on the CON Review Standards for CT, and we urge that the CON Commission initiate the appropriate process to revise these Standards as soon as is possible. We will be pleased to participate in this process as appropriate.

1.+Name: Stanley O. Skarli, MD
2.+Organization: Helen DeVos Children's Hospital
3.+Phone: 616-454-6435
4.+Email: stan@greatlakesneuro.com
5.+Standard: CT
6.+Testimony: I am submitting this testimony in support of the written testimony submitted by Mike Abney of NeuroLogica regarding the CereTom

I am a Pediatric Neurosurgeon at the Helen DeVos Children's Hospital in Grand Rapids. I support the creation of an alternative number of annual scan equivalents for portable CT scanning technology.

This technology will give better care for patients, and I expect it will also reduce the cost per scan by the incidental reduction in empty scanner time, and patient transport as well as reduce increased risk of complications from extubation, loss of lines or monitors that inevitibly accompany these transports.

This technology also adds the capability to perform cerebral perfusion scans, looking at cerebral blood flow, primarily in severely head injured patients with Xenon CT scanning. Though xenon CT has been available previously, it was extremely cost prohibitive, technologically challenging and extremely time intensive, removing an active scanner from clinical use for prolonged periods of time, and hence has infrequently been used prior to the portable scanner's development.

Thank you,
Stanley O. Skarli, MD

NH Testimony

1.+Name: Andrew Farmer
2.+Organization: AARP Michigan
3.+Phone: (517)267-8921
4.+Email: afarmer@aarp.org
5.+Standard: NH
6.+Testimony: AARP's 1.5 million members living and working in the state of Michigan are deeply concerned about the issues and direction of long term care. Many of them currently utilize its services in every community, in facilities and in their own homes, and many others have elders, spouses and other family members of their own who seek choices or struggle with the choices they have already made – or were forced to by systems which for most currently offer little alternative. One estimate of the economic impact of informal caregiving alone in this state tops the figure of $9 billion annually. Our members demand change, more choices as well as better quality and the Michigan Department of Community Health's Certificate of Need Commission wields important authorities to bring about the types of reform our consumer members desire.

AARP Michigan therefore calls on the Michigan Certificate of Need Commission to appoint in 2007 a Standards Advisory Committee charged with responsibilities to include but are not limited to revisions of nursing home and hospital long term care units beds, definitions and methodologies.

Michigan's long term care landscape has entered a historic time of rapid and profound change, driven by unprecedented, major demographic and market forces and spurred by the 2005 Governor's Medicaid Long Term Care Task Force Final Report, which names those forces: calling for important, fundamental changes and improvement in the way the business of delivering long term care services is conceived and conducted in this state. Our current CON definitions, methodologies and standards related to long term care in total are found badly outmoded by these trends and we thus have an opportunity with this process to bring the CON system into alignment with those trends.

The most important change occurring in long term care is the shift away from nursing homes and "beds" themselves as a workable concept defining what might be the center of long term care delivery; the shift already well underway across the United States and in Michigan is toward no such center at all but to an "array" of facility and community based long term care "supports and services" in which nursing home beds are just one delivery mode and choice.

Indeed, the Choice overwhelmingly preferred by consumers across the entire market of elderly and persons with disabilities is home and community based services -- not nursing homes, though many still would like to make that choice too -- and we therefore need a new paradigm for establishing and projecting Need itself, one not hidebound to one "choice," the least popular and least cost-efficient one at that -- as is currently the case, illustrated by a category of testimony outwardly limited here to "Nursing Home and HLTCU Beds."

So AARP Michigan calls on the Commission to appoint a SAC charged with:

-- developing recommendations for changing definitions, methodologies and standards from "Nursing Home and HLTCU Beds" to those which describe and encompass ALL long term care supports and services, from institutional to 'assisted living' to in-home supports and services, for all populations using and seeking such services from the entire array of delivery options.

-- develop policy recommendations to reform existing nursing home bed standards to award future Certificate changes only to those owners with successful, operation-wide track records of regulatory and quality success.

-- other CoN issues may need to be raised in light of the 2005 Governor's Medicaid Long Term Care Task Force Report which call for additional policy development by the SAC.

-- the Commission must make every effort to assure the 2007 SAC it appoints for these purposes is broadly and heavily comprised of consumer representation reflecting the geographic, generational and cultural diversity the emerging long term care market already serves and anticipates in the coming years.

We are very grateful for this opportunity to provide Testimony to the Department of Community Health and its Certificate of Need Commission and look forward to partnering with the success of its work in 2007 and beyond.

Sincerely,

Andrew Farmer
Associate State Director
for Health & Supportive Services
AARP Michigan

1.+Name: Mary M. Ablan, M.A., M.S.W.
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3.+Phone: 517-886-1029
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5.+Standard: NH
6.+Testimony: The Area Agencies on Aging Association of Michigan (AAAAM) represents the 16 regional Area Agencies on Aging (AAAs) that serve older adults and caregivers in the state of Michigan. Michigan's Area Agencies on Aging are part of a nationwide network of over 650 agencies created by federal law (Older Americans Act) and state law (Older Michiganians Act). Advocating for the quality of life of older adults and their caregivers is one of the responsibilities of AAAs as outlined in federal and state law. It is in this statutory role that this testimony is submitted.

For many years, the AAAAM has been a strong advocate for the reform of Michigan's long term care system in all of its aspects. The important work of the Certificate of Need Commission clearly impacts on long term care. The CON Commission now has the unique opportunity to play a role in improving Michigan's long term care system – improvements that will enhance consumer choices and improve quality while at the same time allowing for the expansion of more cost-effective services.

The current Certificate of Need standards related to long term care need a thorough review and rewrite with the goal of recognizing that long term care now includes nursing facility care, home-based services and assisting living. This broader definition of long term care is being embraced by many elected officials and government agencies, including the federal Centers for Medicare and Medicaid Services (CMS).

Michigan citizens also support the goal of providing more cost-effective choices in long term care services. According to a public opinion poll commissioned by the AAAAM in 2003

- 91% of Michigan residents believe that the Governor and Legislature should explore lower-cost alternatives for long term care

- Home-based care is the preferred choice of most Michigan residents (77% prefer home care, 17% assisted living and 2% nursing home care).

- 90% of Michigan residents surveyed want choice options incorporated into the state's long term care system financed by Medicaid.

The poll was conducted in 2003 among 750 randomly selected Michigan residents by W.K. Greene & Associates of Royal Oak, Michigan. The survey has a margin of error of 4 percent.

The AAAAM calls on the CON Commission to appoint a Standards Advisory Committee charged with:

1. Developing recommendations for changing definitions, methodologies and standards from nursing home and hospital long term care unit beds, to definitions that describe all long term care supports and services, including home-based services and assisted living;

2. Drafting policy recommendations to reform nursing home bed standards so that additional bed allowances are awarded only to those owners with a documented track record of providing quality care.

The AAAAM urges the Commission to appoint Standards Advisory Committee members who are representative of all aspects of the long term care system, including consumers. Members of the AAAAM are willing to offer their time and expertise in the pursuit of this challenging and worthwhile effort.

Thank you for the opportunity to submit this testimony. For a copy of the 2003 public opinion poll or any additional information, contact AAAAM Executive Director Mary Ablan, M.A., M.S.W., at (517) 886-1029.

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5.+Standard: NH
6.+Testimony: January 16, 2007

Norma Hagenow, 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 Ms. Hagenow,

This letter is written as formal testimony about the CON Review Standards for Nursing Home and Hospital Long-Term-Care Unit Beds, which went into effect on December 3, 2004. Spectrum Health appreciates the opportunity to comment on these Standards. Spectrum Health suggests that the CON Commission should address the following components of the CON Review Standards Nursing Home and Hospital Long-Term-Care Unit Beds:

Definitions:
Spectrum Health suggests that the current definition of “replacement zone” for Nursing Home and Hospital Long-Term-Care Unit Beds should be reconsidered. The current language may be too restrictive, and we would propose that consideration be given to increasing the three-mile replacement zone in metropolitan counties. This change would open up the possibility of more suitable relocation opportunities not possible under the current 3-mile requirement. This would allow facilities to consider more cost effective and patient-friendly facilities than what could be considered under the existing requirements.

High Occupancy Bed need exception:
The existing Standards to increase beds in a planning area include an exception to the bed need methodology for high occupancy situations. Specifically, if the applicant facility has experienced an occupancy rate of at least 97% for three (3) years and all other long-term care facilities in the planning area also have experienced an occupancy rate of at least 97% for last three (3) years, then the applicant qualifies to add new long-term care beds. This requirement is outdated, for the following reasons: Medicaid has eliminated “hospital leave days,” making achievement of 97% occupancy even more difficult; and Nursing home cost reporting is maintained retrospectively for only two (2) years making verification of a three-year utilization trend harder to verify. Furthermore, a facility experiencing high demand should not be penalized by low occupancy facilities elsewhere in the planning area. As a result, Spectrum Health suggests that the

language in the standards be changed so that the high occupancy is specific only to the applicant facility. Specifically, we propose that the high occupancy requirements for increasing long-term care beds be changed to an occupancy requirement of 90% for the applicant facility for two (2) years, and that occupancy requirement for the rest of the planning area be eliminated. This change would be consistent with high-occupancy provisions in the Hospital Bed Standards.

Special Population groups:
The Commission has identified several categories of special population groups, which are deserving of special attention in the CON Review Standards. There is a notable population category, which is currently absent: patients with psychiatric diagnosis. With the closing of the State psychiatric facilities, and the reduction in residential psychiatric capacity Statewide, many of these patients are seeking admission to licensed nursing homes. These patients require additional behavioral management techniques. We believe that because of the special needs of this patient population they would be better served in a specialized program not currently offered in general nursing home units. Therefore Spectrum Health suggests the addition of a Special Population group for long-term patients with psychiatric diagnoses.

New Design Pilot Program:
Currently the CON standards require that pilot nursing home projects qualifying for the "new design pilot program" include at least 80% single occupancy resident rooms with adjoining bathrooms serving no more than two residents in both the central support inpatient facility and any supported small resident housing units. If the pilot project is for the replacement/renovation of an existing facility and utilizes only a portion of its currently licensed beds, the remaining rooms at the existing facility shall not exceed double occupancy. Spectrum Health would like to omit the requirement that remaining rooms at the existing not exceed double occupancy. This requirement can make it difficult for facilities to renovate under the Design Pilot Program, especially if they have rooms throughout the facility that exceed double occupancy. For example, if a facility would like to renovate four (4) floors, one (1) floor at a time, and the floors have rooms that exceed double occupancy it would be very difficult because the facility would have to take several beds off-line in order to meet the 80% single occupancy requirements of the pilot program. Most facilities cannot afford to take several beds off-line at the same time. Therefore, in order for an existing facility to renovate under the pilot program and thus maximize facility space and beds for potential patients, this requirement should be omitted from the CON standards. Spectrum Health appreciates the opportunity to share our views on needed improvements to the CON Review Standards for Nursing Home and Hospital Long-Term-Care Unit Beds.
Sincerely,

Meg Tipton
Strategic Regulatory Associate

1.+Name: RoAnne Chaney
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5.+Standard: NH
6.+Testimony: I represent the MI Disability Rights Coalition (MDRC). I also served as Chair of the Governor's Medicaid Long-Term Care Task Force. The Task Force report issued in July 2005 characterizes long-term care as an array of supports and services which should have broader availability. The current CoN definitions, methodologies and standards related to long term care are very outdated and inconsistent with the current definition of long-term care as a an array of services and supports which includes not jut a bed in a nursing home, but also assisted living, specialized care such as memory care, home care and everything in between. the opportunity that exists now with this process is to update the CoN system into alignment with those trends. The process of establishing "need" for long-term care needs to be an inclusive process to assess "need" across the array and spectrum of services rather than creating beds and pressure to fill them.

In addition, MDRC call upon the CoN process to stop allowing the establishment of "beds" in facilities own by companies or owners that have a history of serious citations that place individuals at great risk of harm or that directly cause harm or injury.

Thank you for this opportunity to provide this testimony.

Truly.

RoAnnne Chaney, MPA
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1.+Name: Sara M. Duris
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5.+Standard: NH
6.+Testimony: On behalf of the Alzheimer's Association Michigan Council, I am submitting comments requesting that the Michigan Certificate of Need Commission appoint a Standards Advisory Committee (SAC) charged with responsibilities to include but are not limited to revisions of nursing home and hospital long term care units' beds, definitions and methodologies.

Persons with dementia and their families need to have a greater variety of choices for long term care services. Most people with Alzheimer's disease or a related disorder (71%) live in the community and this is the preference of the majority of families. Due to the length of the disease process, the high cost of the disease, and the lack of supports for caregivers trying to keep people with dementia at home, many people use up their assets and are forced to move from their home or a community care setting into a nursing home where the costs are covered by Medicaid. We believe it can be a significant cost savings to provide long term care services to people in a home or community based setting. The average annual cost of nursing home care in urban areas is now $70,000. The average cost of paid home care for people with dementia at home, to supplement the unpaid work of family caregivers, is $19,000 a year.

The Alzheimer's Association participated in formulating the 2005 Medicaid Long Term Care Task Force Report through work group involvement and individual testimony. We urge the adoption of the Task Force's recommendations, which include increased nursing home transition services and money follows the person principles. We continue to partner with the Michigan Department of Community Health, the Long Term Care Commission and other stakeholders as we work to transform long term care services in Michigan. The Certificate of Need Commission can play a vital role in bringing about the types of reform the Governor's Task Force recommended and our clients desire to see happen.

The Alzheimer's Association joins other groups in calling for the appointment of a SAC which will:

-- develop recommendations for changing definitions, methodologies and standards from "Nursing Home and HLTCU Beds" to those which describe and encompass ALL long term care supports and services, from institutional to 'assisted living' to in-home supports and services, for all populations using and seeking such services from the entire array of delivery options.

-- develop policy recommendations to reform existing nursing home bed standards to award future Certificate changes only to those owners with successful, operation-wide track records of regulatory and quality success.

-- develop policy on other CON issues which are raised in light of the 2005 Governor's Medicaid Long Term Care Task Force Report.

The Commission must make every effort to assure the 2007 SAC it appoints for these purposes is broadly and heavily comprised of consumer representation reflecting the geographic, generational and cultural diversity the emerging long term care market already serves and anticipates in the coming years. The Alzheimer's Association would be pleased to provide input as well as recommend consumers who could participate.

Thank you for your consideration of these comments.

Sara M. Duris
Public Policy Coordinator
Alzheimer's Association Michigan Council
530 Paw Paw Avenue
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1.+Name: Scott Heinzman
2.+Organization: ADAPT Michigan
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4.+Email: sheinzman@twmi.rr.com
5.+Standard: NH
6.+Testimony: ADAPT has worked since the passage of the Americans with Disabilities Act (ADA) to end institutional bias within Medicaid long term care programs. The Supreme Court's Olmstead decision confirmed individuals are entitled to receive LTC services and supports in the least restrictive setting appropriate to their needs. This has led to a contradiction in practice as Medicaid rules still require states apply for waivers to fund home and community based LTC programs.

When given a real choice, many people would prefer to remain in their own homes when they require LTC services. ADAPT demands an end to all practices which restrict a person's ability to receive LTC services in the setting of their choosing.

We believe the Certificate of Need (CON) Commission can help consumers meet this goal.

The Commission has the authority to appoint a Standards Advisory Committee. We would like to see an SAC created.

We further ask the SAC be charged to align the CON process of definitions, methodologies and standards for nursing home and HLTCU beds to reflect all long term care options desired by consumers. We believe the recommendations from the 2005 Governor's Medicaid Long Term Care Task Force Report serves as a blueprint for direction of this alignment.

The SAC should be constituted with a majority of consumers reflecting age, types of disability and geographic diversity inherent to long term care consumers.

Lastly, all future CON standards must not reward owners and those affiliated with institutions who have a track record of neglect, abuse or other regulatory or legal violations which had had an adverse affect on consumers. We expect a process which weeds out all bad actors.

Thank you for accepting this comment.

Sincerely,

Scott Heinzman
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NICU Testimony

1.+Name: Robert Meeker
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5.+Standard: NICU
6.+Testimony: This is Spectrum Health's formal testimony about the CON Review Standards for NICU Services, which went into effect on June 4, 2004. We appreciate the opportunity to comment on these Standards.

NICU Bed Need.

The NICU Bed Need formula for the state has remained unchanged for decades. Essentially, it asserts the need for 4.5 NICU beds per 1,000 live births across the state, with regional adjustments for the percentage of births < 1,500 grams. The continued validity of this need ratio needs to be re-evaluated. Recent trends have revealed an increase in the rate of premature births and in the survival rate for premature babies. Both these factors increase utilization of NICUs. Hence, the need formula should be re-examined.

Expansion of NICUs with large number of referrals from other NICUs.

The current standards include a provision to allow existing NICUs to expand beyond the numbers of beds needed in their region if they receive a disproportionate number of admissions from other NICUs. This provides highly specialized NICUs additional capacity to receive a large number of referrals from other facilities. As currently stated, however, this provision is limited to five (5) additional NICU beds. While providing some additional capacity to referral NICUs, this arbitrary cap represents an unnecessary restriction on the ability of tertiary neonatal centers to adequately accommodate referrals received from other NICUs. Spectrum Health respectfully suggests that the limit of only five (5) additional NICU beds under this provision be removed from the CON Standards. Furthermore, since referrals from other NICUs are defined as being beyond the "normal" neonatal bed need in a region, the acute care beds used for NICU service to patients from other NICUs should also be considered as being outside the calculated acute care bed need in a planning area. Therefore, we further recommend that NICU beds awarded on the basis of a high referral rate from other NICUs not be required to be taken from the existing acute care license of the requesting hospital. Rather, these beds should be considered to be additional licensed capacity for the hospital.

Project Delivery Requirements – Necessary Sub-Specialists.

The project delivery requirements for NICU, identified in Section 11 of the CON Review Standards, specify in subsections (1)(c)(ix) & (x) various medical subspecialties for which on-site and consultation provisions must be made by the operator of NICU services. Most appropriately, these specialties should be specific to pediatrics; for example: pediatric cardiology, pediatric ophthalmology, etc. Since these specialists will be required to provide services for the smallest and sickest pediatric patients, they should have training and experience in practicing their specialties for children.

Spectrum Health appreciates the opportunity to comment on the CON Review Standards for NICU Services, and we urge that the CON Commission initiate a process to revise these Standards as soon as is possible. We will be pleased to participate in this process as appropriate.

UESWL Testimony

1.+Name: Alan Buergenthal
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5.+Standard: UESWL
6.+Testimony: This letter is written as formal testimony about the CON Review Standards for UESWL Services, which went into effect on June 4, 2004. Greater Michigan Lithotripsy (GML) appreciates the opportunity to comment on these Standards. GML is a partnership involving hospitals and physicians established to provide mobile lithotripsy services to the citizens of Michigan. We are involved in three (3) mobile lithotripsy routes in the state, serving more than a dozen host sites in lower Michigan. We have asked our management company, American Kidney Stone Management, Ltd. (AKSM), 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 50 mobile and fixed-site lithotripters for some 20 independently-owned companies across the country. Nationwide, on average, a mobile lithotripter performs 600 cases per year. The maximum number of cases performed on any single mobile lithotripter is 1,200 cases. Generally speaking, once case volume exceeds 1,000 cases per machine, a second mobile lithotripter is added. After a mobile route adds a second lithotripter, overall route volume increases. This is because a single mobile lithotripter treating 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 route doing 1,000 or more annual treatments, the result is that patients have their treatments postponed or are treated invasively. AKSM's fixed-site lithotripters, on the other hand, typically treat no more than 1,500 cases per year. 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. We recommend that a volume requirement more consistent with national experience, as cited above, should be incorporated into the CON standards for expansion of a mobile lithotripsy route. 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 the expansion requirements in these Standards. We will be willing to participate in this process as appropriate.

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6.+Testimony: This is Spectrum Health's formal testimony about the CON Review Standards for UESWL Services, which went into effect on June 4, 2004. We appreciate the opportunity to comment on these Standards.

Predominance of Mobile Services.

During the time since substantial changes were last made to the CON Review Standards for UESWL Services, there has been a significant transformation in the way lithotripsy services are delivered in Michigan. At that time, fixed lithotripsy sites comprised at least half of the service capacity in the state. Currently, all formerly fixed site services have converted to mobile services. This transformation is consistent with national trends and was made possible by the later generation lithotripsy machines which are more compact and portable than their predecessors. The current generation mobile lithotripters fit in a regular-sized van and can be wheeled conveniently into existing operating rooms, eliminating the need for dedicated lithotripsy space and cumbersome equipment in healthcare facilities. This transformation in the delivery of lithotripsy services indicates the need for changes in the CON Review Standards for UESWL Services. As a result of the increase in mobile UESWL routes, delivery of lithotripsy services at ambulatory care sites increasingly makes sense. Several of the existing lithotripsy routes have host sites at ambulatory surgical centers. Given this trend, an examination of the required on-site services may be warranted. While most are reasonable, some of the requirements may preclude

mobile lithotripsy services from being delivered at some otherwise capable ambulatory surgical centers (e.g. the requirement for a 23-hour holding unit). These on-site requirements should be reassessed. In a similar vein, the requirement in Section 11(1)(e) for "a properly prepared parking pad for the mobile unit…, waiting area for patients, and a means for patients to enter the vehicle..." does not apply, since contemporary UESWL units are transported directly into operating rooms, rather than requiring patients to walk into a mobile trailer. In Section 4, which specifies the requirements for replacing existing UESWL units, there are several special provisions for replacing existing fixed lithotripsy machines with new mobile units. Given the absence of fixed lithotripters in the state, Subsection 4(3) could be eliminated in its entirety, as could Subsection 4(6).

Expansion of existing lithotripsy services.

The requirement for expansion is 1,800 procedures per unit in a service. This is an extremely high level to maintain, especially with a mobile service which may travel substantial distances, requiring significant time on the road. Given that all UESWL units in Michigan are mobile, this unreasonably high volume requirement should be re-evaluated. Furthermore, whatever volume standard is adopted, provisions should be made for high-demand services, as demonstrated by long backlogs and/or large numbers of temporary stents.

Need Methodology.

It has been several years since the adjustment factor in Appendix A has been recalculated. This factor is the ratio of UESWL procedures performed in the state to the number of kidney stone discharges from Michigan Hospitals. As the prevalence of lithotripsy services increases, hospital discharges related to kidney stones should decrease commensurately, resulting in a significant increase in the adjustment factor. Spectrum Health urges that this adjustment factor be recalculated during the current process of updating the UESWL Review Standards.

Replacement Definition.

The definition of "replace/upgrade a UESWL unit" contained in the existing standards is vague and should be made clearer and more specific. Many other CON review standards include a specific cost which differentiates between simple equipment maintenance and updating, on one hand, and significant upgrading or replacement on the other. In the case of lithotripters, an amount of $250,000 over a 2-year period would appear to be reasonable.

Spectrum Health 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 will be pleased to participate in this process as appropriate.
Sincerely,

Multiple Services Testimony

>>> <DoNotReply@michigan.gov> 1/16/2007 4:16 PM >>>
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Certificate of Need Commission
Public Hearing Testimony
January 16, 2007
The Economic Alliance for Michigan,
the statewide business-labor coalition

The Economic Alliance for Michigan continues to staunchly support the Certificate of Need Program and its processes. In this case, we specifically support the statutorily-required process that requires revision of the CON standards at least every 3 years AND more frequently as indications to Commission that more frequent changes are needed. We commend all stakeholders in this process for their difficult, diligent work in these endeavors.

CT Scanners
The CT standards are very imprecise. Contrary to prior expectations of diminishing utilization with decreased cost; over the past few years this modality has evolved, with many advanced, specialized, costly CT units. The physician commitment methodology must be strengthened similar to MRI and surgical standards (not commit volume from a site that is not making volume). In addition, the CT methodology needs to be consistent with MRI and PET standards where the physician committed volumes are based on actual utilization, not unverified projected future utilization. Finally, there is a need to implement an appropriate realistic geographic constraint on distance of the volumes to be committed volumes.

We also strongly support having a deliberative process in place for specialized CT applications; to evaluate whether standards are needed as well as differential requirements regarding volume, cost, quality, etc. We believe that consumers, purchasers, payers and providers benefit from advance guidance regarding CON requirements for these specialized applications. A major but unfulfilled purpose of the 1988 CON law was to implement CON standards for new technology or new application of established technology PRIOR to the sale
of new units. As CT components are being added to other imaging and therapy modalities such as the PET/CT hybrid units, CON standards should address how to handle these cases,. For example, MRT and future MRI units include CT technology, not to mention the many other mini-CTs that are now coming on the market.

UESWL Services
Although this does not appear to be the trend, there is no language regarding conversion of mobile to fixed units.

Air Ambulance
The expansion language needs to be addressed, as it is easier for a new applicant to initiate service than for an existing provider to expand, thereby diminishing economies of scope and scale.

Nursing Home and HLTCU Beds
There is a need to address programmatic issues such as not allowing existing providers with numerous violations to acquire other homes as well as requiring applicants to meet the Michigan building codes.

Thanks for providing us this opportunity to speak to these issues. Again, we commend the Commission for its deliberative processes. CON continues to need to stay focused on key issues.