1. Name: Judith Kettenstock
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5. Standards: AA
6. Testimony: October 27, 2009

Midwest Medflight would like to once again comment on the proposed revisions to the CON Review Standards for Air Ambulance Services. We are commenting on the proposed standards, which were approved for public comment by the CON Commission on June 13, 2007. In general, Midwest Medflight was supportive of the proposed changes at that time and continue to be supportive of them.

We would especially like to emphasize the following section that was proposed for Section X. An applicant proposing to change the base of operations of an existing air ambulance shall:

Sec. X. An applicant proposing to change the base of operations of an existing air ambulance shall:

(1) demonstrate that in the most recent 12-month period for which verifiable data are available to the Department, the air ambulance service met one (1) of the following:.

(a) 275 patient transports for an air ambulance service with one (1) air ambulance;

(b) 600 patient transports and organ transports for an air ambulance service with two (2) air ambulances, of which 550 must be patient transport;

(c) 1,200 patient transports and organ transports for an air ambulance service with three (3) air ambulances, of which 825 must be patient transport;

(d) 1,800 patient transports and organ transports for an air ambulance service with four (4) air ambulances, of which 1,100 must be patient transport.

(2) maintain the same base hospital(s) of the existing air ambulance service.

(3) identify the proposed base of operations, and comply with all of the following:

(a) provide a letter of support from the medical control authority for the proposed base of operations indicating that the applicantÆs protocols comply with the requirements of the medical control authority;

(b) demonstrate that all existing air ambulance services with a base of operations within a 75-mile radius of the proposed new base of operations of the air ambulance service have been notified of the applicant's intent to change the base of operations, by means of a certified mail return receipt dated before the deemed complete date of the application; and

(c) demonstrate that the proposed new base of operations is within the same health service area as the existing base of operations.

This section as it currently stands in the proposed changes would prohibit Midwest Medflight from operation out of its current hangar at Willow Run Airport or operating out of another hangar if a change was required. The proposed

wording submitted by Spectrum Health in 2007 would allow us to continue to operate and make changes if financially we were required to do so.

We would like to strongly recommend that the state convene a committee to closely examine the need for any further aircraft in the State of Michigan with the current economic situation and several under utilized resources already available in the state.

Thank you for the opportunity to comment on the proposed revisions to the CON Review Standards for Air Ambulance Services.

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5. Standards: NICU
6. Testimony:

October 27, 2009

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

Dear Mr. Goldman,

This letter is written as formal testimony about the CON Review Standards for NICU Services, which went into effect on November 13, 2007. Spectrum Health appreciates the opportunity to comment on these Standards.

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 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 could 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 capacity for the hospital.

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.

Sincerely,

Robert A. Meeker
Strategic Program Manager

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Testimony
Blue Cross Blue Shield of Michigan/Blue Care Network
CON Public Hearing
October 20, 2009

Thank you for the opportunity to provide testimony on behalf of Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network (BCN). BCBSM and BCN continue to support and actively participate with the Certificate of Need (CON) program. This program has become increasingly significant based on its design to ensure the delivery of cost-effective, high quality health care to Michigan residents.

BCBSM/BCN Recommendations Regarding Standards for Review during 2010

- Neonatal Intensive Care Services/Beds (NICU): The decrease in population and births in Michigan raises the question whether there is overcapacity of NICU in the state. BCBSM/BCN recommends that the CON Commission convene a SAC to evaluate these standards and assess whether or not over-capacity exists in the state, and if so, what can be done to ensure that additional NICU services/beds are not added to the current supply.

- Nursing Home and Hospital Long-Term-Care Unit/Beds: Feedback from the Nursing Home/Long Term Care community (providers and consumers) demonstrates much interest in modifying these standards. Based on our position of supporting open discussion, BCBSM/BCN supports these stakeholders in this effort and if desired by this group, supports the CON Commission in convening a SAC to review these standards.

- CT Scanner Services: BCBSM and BCN have concerns based on the proliferation of numbers, types and locations of CT units and escalating utilization volumes. BCBSM/BCN, thus, recommends that CT Scanner Services CON standards be thoroughly evaluated, and the CON Commission convenes a SAC to do so.

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CON Commission Actions

Proposed MRI CON Standards

BCBSM and BCN support the final action on the MRI simulation language but do not support the final ER language or the charity care provisions still being discussed:

- BCBSM supports the (final) language that exempts MRI units used to simulate megavoltage radiation treatment for cancer. Our clinical group, the BCBSM/BCN collaborative, believes that this is an important component of effective treatment by allowing for more accurate treatment planning, thus yielding higher quality services for patients
- BCBSM and BCN do not support the (final) language that allows replacement of a mobile MRI with a fixed MRI for any hospital emergency room with more than 20,000 visits per year. Based on the input of the BCBSM/BCN clinical collaborative, we feel that there is no public policy rationale for this approach as the majority of MRI services do not need to be completed immediately upon arrival in the emergency department, and in those case where a scan is able to be performed immediately, may be no capacity at such facilities to treat the findings of a positive MRI.

- BCBSM and BCN do not support the concept of replacing mobile MRI units with fixed MRI units for freestanding for-profit imaging centers that provide at least 25% of their service to Medicaid–covered patients. Many questions remain regarding the validity of this proposal from a public policy rationale. Specifically, this additional capacity would be in direct competition with existing hospital-based not-for-profit MRI units, including patients with other types of coverage than Medicaid.

Conclusion

BCBSM and BCN continue to support the CON program and the ongoing review of the standards in terms of cost, quality and/or access concerns. We applaud the CON Commission and MDCH staff as they continue to facilitate an objective review process, by eliciting in-depth clinical expertise as well as input from consumers, purchasers, and payors. BCBSM and BCN will continue to be an open-minded, active participant in these endeavors. As always, BCBSM/BCN commends the CON Commissioners and MDCH staff for their diligent efforts in maintaining CON as a strong, vibrant program to help ensure the delivery of high quality, safe and effective care to patients across the state.

10/19/09

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6. Testimony:

DRAFT

October 27, 2009

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

Dear Mr. Goldman,

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 June 20, 2008.

The revised Standards went into effect only last year. Although Spectrum Health did not fully concur with the changes made at that time, we suggest that they have been in effect for too short a period of time to determine their effectiveness. Therefore, Spectrum Health recommends that no changes be made to the CON Standards for NH and LTC Beds at this time

Spectrum Health appreciates the opportunity to comment on these Standards.

Sincerely,

Meg Tipton

Strategic Regulatory Associate

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HCR·ManorCare

Supplemental Testimony re Nursing Home and Hospital Long-Term Care Unit Beds
Re: MDCH Public Hearing on Certificate of Need (CON) Review Standards
October 20, 2009

HCR Manor Care, Inc., on behalf of its subsidiary operating companies in Michigan, ("HCR") submits the following supplemental testimony in support of a limited re-opening of the CON Review Standards for Nursing Home and Hospital Long-Term Care Unit Beds. HCR ManorCare is a national long-term care provider with 28 nursing home facilities in Michigan. Through our legal counsel, Phyllis Adams, Dykema Gossett, HCR submitted initial comments during the public hearing that as held on these and other CON Review Standards on October 20, 2009. Our supplemental testimony below includes more specific suggestions as to potential revisions to these Standards.

First, as outlined in our prior testimony, HCR supports revisions to the comparative review criteria in the current CON Standards. These criteria received limited attention by the Standard Advisory Committee during the most recent revisions. These criteria could be improved significantly to include standards that favor and incentivize innovation, quality of care, and investment in technological improvements for nursing home facilities. The comparative review criteria could be a valuable way to raise the bar for new nursing homes or nursing home expansions in Michigan.

The Commission should consider criteria that would reward applicants that seek to construct facilities that promote quality and innovation, including:

- Award points for proposed use of electronic health record technology, including systems that provide for immediate patient documentation that goes directly into patient medical records.
- Award points for incorporation of wireless internet capabilities in proposed facilities.
- Award points to facilities that propose internet accessible computer stations for residents, as increasingly, residents are computer savvy and use the internet to maintain contact with their care givers/community physician, family members, clergy or others.

- Award points for facility designs that incorporate more sophisticated therapy suites/spaces and specialized equipment for patients with high acuity and rehabilitative needs.
- Award points for facilities proposing to serve a higher percentage of patients receiving specialized rehabilitation services, to address facilities serving the needs of high-acuity, post-hospital skilled nursing patients.
- Award points for programs that address licensed nurse retention, with specific criteria for acceptable programs included in the Comparative Review Criteria, given that decreasing licensed nurse turnover has been directly linked to improvements in quality of care.
- Improve description of "culture change" in the Comparative Review Criteria so that points would only be awarded to applicants that satisfy specific criteria, including investments in the physical plant of the facility that promote resident independence and facilitate successful resident rehabilitation and discharge back to the community.
- Award points if the applicant has an independent advisory committee on quality.
- Award points if the applicant has, or proposes to use as evidenced by a signed commitment, nationally recognized programs/vendors that benchmark indicators of quality and/or systems that track patient outcomes.

Similarly, points should be deducted from applicants whose projects are not congruent with overall quality and other public policy objectives for long-term care, including:

- Deduct points from applicants that propose to establish (through an initial request for beds or through expansion) very large nursing homes, given that the CON Commission's own "new design model" encourages smaller nursing home facilities. For example, the CON Standards could prevent MDCH from accepting a CON application seeking to establish a nursing home with more than 200 beds. The Comparative Review Criteria also could disfavor large nursing homes by deducting points as follows:

  180 – 190 beds = deduction of 4 points
  190 – 200 beds = deduction of 6 points

200 – 210 beds = deduction of 8 points
210 – 220 beds = deduction of 10 points
220 – 230 beds = deduction of 12 points
230 – 240 beds = deduction of 14 points
240 – 250 beds = deduction of 16 points

Second, HCR supports limited revisions to the high occupancy language in Section 6(1)(d)(ii) of the Standards. Some appropriate changes were made to this Section during the last revisions effective in June 2008. These changes allow a facility to qualify for high occupancy without being tied to all other nursing homes in the planning area and allow the applicant's occupancy rate to be averaged over the most recent 12 quarters of operation. However, even with those revisions, the high occupancy exception is still nearly impossible to satisfy because of the 97% occupancy threshold that applies uniformly to all buildings. The intent of the high occupancy exception is to allow successful buildings to get additional beds, which helps decrease public dependence on poor performing facilities.

Consistent with testimony offered by Aging Services of Michigan, HCR supports a high occupancy exception under Section (6)(1)(d)(ii) of the Standards based on 94% occupancy for 12 months/4 consecutive quarters. HCR also supports a high occupancy exception of 91% occupancy for smaller buildings of 55 beds or less. Under the current Standards, there is a mathematical disadvantage for smaller facilities given that one or two unoccupied beds, even for a short period, have a disproportionate impact on occupancy for an entire quarter.

With respect to relocation of nursing home beds, HCR believes that the restrictions in Section 7 of the CON Standards are unnecessary and unrelated to any objective standards or criteria. Specifically, allowing beds to be relocated from a "donor" facility only once every seven (7) years is wholly arbitrary and unrelated to any factual evidence that more frequent relocations may be against the public interest. Relocation of beds to facilities seeking additional beds may help to "right size" facilities within a planning area without increasing the total supply of licensed beds. Additionally, the current Standards may actually prop up poor performing nursing homes that have excess licensed beds, thereby resulting in a distribution of beds in the planning area that does not respond to local needs.

The current Standards also prohibit more than 50% of the licensed beds at the donor from being relocated. Again, this standard is arbitrary and irrational as there is no evidence that this

would result in an appropriate number of beds at the "donor" facility to ensure ongoing quality of care. For example, an 80 bed facility could be reduced to 40 beds, which would probably be highly inefficient. On the other hand, a 360 bed facility could be reduced to 180 beds, which may still be too many beds to support quality operations, particularly in an old or obsolete building. Additionally, after seven (7) years, a 40 bed facility could relocate 50% of its beds again and have only 20 beds remaining. If necessary or appropriate, this standard could require a "critical mass" of beds to remain at the "donor" facility to address concerns that the number of beds left at the donor would be insufficient for quality operations. However, if that approach is used, criteria should be developed based on industry literature and published studies as to the relationship between nursing home size and quality of care and/or financial feasibility.

Finally, the CON Commission may wish to consider adding language to the Standards to incorporate two successful concepts from other CON States as follows. First, a number of States, including Maryland, New Jersey, Delaware and Illinois, permit existing facilities to add up to 10 beds or 10% of the licensed capacity, whichever is less, every 2 years. These small, incremental bed projects are subject to a CON exemption or waiver although this concept could be incorporated into the Michigan regulatory framework by requiring only nonsubstantive review for such applications.

Second, several other States, including Maryland, conduct a pre-licensure CON certification review to ensure that the proposed project has been implemented consistent with the CON decision before a health facility license is issued. This requirement may add "teeth" to the enforcement of some of the applicable CON Standards/criteria.

Thank you for this opportunity to comment on the CON Standards for Nursing Home and Hospital Long-Term Care Unit Beds.

Sincerely,

Lisa S. Rosenthal
Director of Health Planning
HCR ManorCare

Submitted October 26, 2009

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5. Standards: NH
6. Testimony: See attached document.

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October 27, 2009

Ed Goldman
CON Commission Chairperson
Capitol View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Goldman,

The Health Care Association of Michigan represents 260 nursing facilities across the state including county medical care facilities and hospital long term care units. The Certificate of Need Standards applicable to our members is currently up for review under the normal three year process. These standards were reviewed and updated in March 2008; and further revised in June 2008. The standards that are before us now have been in place for about 16 months.

The prior review of these standards which began in the summer of 2007 and concluded in March/June 2008 made significant changes. Some of these changes were: the addition of quality measures, outstanding liabilities owed the department, related organizations, addendum for pilot projects was incorporated into the standards, comparative review rewritten, relocation of beds policy added to the standards, high occupancy criteria changed, special population beds changed to reflect current needs and the bed need by planning area was updated and recomputed. This is an impressive list incorporating the greatest changes to the standards in decades.

HCAM would recommend at this time the standards not be reopened for review for two primary reasons. The reasons are that the standards underwent an extensive review which included numerous changes as detailed above in 2008. This number of significant changes needs time to determine the impact and only about 16 months have passed. Also, appeals regarding these current standards and some carrying over from the prior standards are yet to be finalized. It seems more time is needed to evaluate the effectiveness of these standards before more changes should be recommended.

If the Commission desires to move ahead with a Standards Advisory Committee HCAM could support a SAC with a very limited charge and an equitable representation of the long term care groups. The comparative review section of the standards provides little differentiation between applicants. This section could be adjusted to create a better comparison.

Thank you for the opportunity to provide testimony on these standards. If you should have any questions please contact Pat Anderson of my staff at 517-627-1561 or email patanderson@hcam.org.

Sincerely,

David LaLumia
President/CEO

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Testimony
Blue Cross Blue Shield of Michigan/Blue Care Network
CON Public Hearing
October 20, 2009

Thank you for the opportunity to provide testimony on behalf of Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network (BCN). BCBSM and BCN continue to support and actively participate with the Certificate of Need (CON) program. This program has become increasingly significant based on its design to ensure the delivery of cost-effective, high quality health care to Michigan residents.

BCBSM/BCN Recommendations Regarding Standards for Review during 2010

- Neonatal Intensive Care Services/Beds (NICU): The decrease in population and births in Michigan raises the question whether there is overcapacity of NICU in the state. BCBSM/BCN recommends that the CON Commission convene a SAC to evaluate these standards and assess whether or not over-capacity exists in the state, and if so, what can be done to ensure that additional NICU services/beds are not added to the current supply.

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CON Commission Actions

Proposed MRI CON Standards

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- BCBSM and BCN do not support the concept of replacing mobile MRI units with fixed MRI units for freestanding for-profit imaging centers that provide at least 25% of their service to Medicaid–covered patients. Many questions remain regarding the validity of this proposal from a public policy rationale. Specifically, this additional capacity would be in direct competition with existing hospital-based not-for-profit MRI units, including patients with other types of coverage than Medicaid.

Conclusion

BCBSM and BCN continue to support the CON program and the ongoing review of the standards in terms of cost, quality and/or access concerns. We applaud the CON Commission and MDCH staff as they continue to facilitate an objective review process, by eliciting in-depth clinical expertise as well as input from consumers, purchasers, and payors. BCBSM and BCN will continue to be an open-minded, active participant in these endeavors. As always, BCBSM/BCN commends the CON Commissioners and MDCH staff for their diligent efforts in maintaining CON as a strong, vibrant program to help ensure the delivery of high quality, safe and effective care to patients across the state.

10/19/09

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October 26, 2009

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

Re: Public Hearing for CON Review Standards up for Review in 2010

Dear Chairman Goldman,

I am writing to provide public comment on the Certificate of Need Review Standards for Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services pursuant to the Notice of Public Hearing posted on the Michigan Department of Community Health website. I understand that as part of this review, the CON Commission is tasked with evaluating whether or not each covered clinical service should remain regulated under the Certificate of Need program. I am writing to encourage the continued regulation of UESWL services and to provide you with support for doing so.

First let me start by explaining my expertise in this area. I am the Chief Executive Officer of United Medical Systems (DE), Inc. (UMS), minority owner of Great Lakes Lithotripsy. UMS provides mobile UESWL (aka lithotripsy) across the United States. In Michigan, UMS owns and manages four mobile lithotripsy routes through several subsidiaries. UMS has been providing transportable lithotripsy services in the United States since 1996 and in Michigan since 2001.

Certificate of Need was established throughout the U.S. and specifically in Michigan, to ensure access to high quality healthcare services while controlling increases in cost. Lithotripsy is a healthcare service that benefits from these regulations in many different ways.

Certificate of Need provides for oversight of lithotripsy at a time when more quality monitoring is needed, not less. Through the CON Annual Survey, the State collects lithotripsy treatment and retreatment data for every facility providing this service. Nationally we have been seeing an increase in re-treatments, despite improvements in technology which should be leading to improvements in quality and decreases in the need for re-treatments. This is something that should be looked at more closely and deregulating lithotripsy at this time would be a step in the wrong direction.

Unfortunately, lithotripsy and other outpatient services may often be areas in which abuse can occur. In states that do not cover lithotripsy under their CON program or do not have CON, physicians may obtain lithotripters more easily and may have a direct financial incentive to perform more lithotripsy procedures. It has been our experience that in such states, physician groups are very willing to acquire their own lithotripters and thus be more directly dependent upon their own referrals, and perhaps more likely to engage in abusive activities. CON in Michigan serves to prevent and deter every physician group from owning their own lithotripter, thus allowing the conservation of health care capital needed for equipment, and CON requirements in Michigan encourage ownership by multiple groups in turn lessening the likelihood that a single physician group will have sole direct ownership. The current system still allows for some physician ownership, but encourages a situation where several groups share joint ownership. In situations of joint ownership by multiple groups, a non-physician managing partner is usually involved to manage the lithotripsy services and the needs of the multiple groups. The managing partner brings an additional element of control and compliance to the lithotripsy operations, and the broadly based ownership dilutes further the direct impact that any individual physician may receive based upon his or her personal referrals.

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Certificate of Need also has encouraged lithotripsy to become a mobile service in Michigan by requiring multiple inpatient facilities to collaborate and commit MIDB data to the application. Pushing lithotripsy to mobile service has led to a more efficient and effective means of providing this service to Michigan patients. Because lithotripsy is not a high volume service at any one individual location, it is ideally suited for mobile service. One lithotripsy unit can provide service to multiple locations. Rather than each hospital purchasing this expensive piece of equipment and only utilizing it a few days a month, they can instead obtain the services from a mobile service provider and share the costs with all of the other facilities receiving service on that route. This creates additional efficiencies for the facilities themselves because it encourages them to schedule all of their lithotripsy procedures together on the days they have service available. It also increases access to the service by making it cost effective for more hospitals to provide the service across the State.

Certificate of Need is also tasked with ensuring quality healthcare for the residents of Michigan. Although there can be a lot said for the need to have high quality diagnoses, when we look at CON regulation of CT, MRI, and PET, the need for high quality treatments is at least as important, if not more. So much of quality, when it comes to MRI and CT, is in the interpretation of the image, not the performance of the scan itself. With lithotripsy it is exactly the opposite. The quality lies in the performance of the procedure itself, which is ensured by the project delivery requirements in the Certificate of Need standards which require appropriate training and credentialing for urologists performing lithotripsy procedures.

Although Certificate of Need typically regulates the most expensive pieces of medical equipment, it is appropriate for CON to regulate lithotripsy despite its relatively inexpensive equipment cost because of the relatively high procedure costs billed to insurance companies and patients. Lithotripsy procedures are billed at a rate of $2,800.00 to $7,500.00, depending on geography and insurance carrier. Certificate of Need is not only about limiting health facilities capital expenditures, it is truly about keeping the costs of health care to patients and insurance companies in check. Without oversight from regulatory bodies, like Certificate of Need, we will see physicians purchasing their own equipment and overutilization of the service, resulting in increased costs to payers.

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

Cordially,

Jorgen Madsen
CEO

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6. Testimony:

October 27, 2009

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

Dear Mr. Goldman,

This letter is written as formal testimony about the CON Review Standards for UESWL Services, which went into effect on February 25, 2008. 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 two (2) dozen host sites in Lower Michigan. We are concerned that the number of cases required to expand the number of lithotripsy units on a mobile route is excessive and results in insufficient access to this service for the residents of the state.

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 to a mobile route.

After a mobile route adds a second lithotripter, overall volume increases. This is because a single mobile lithotripter treating more than 1,000 cases annually is subject to increased down time for maintenance and is unable to be physically transported in a timely fashion to satisfy the required demands of dispersed communities. If another machine is not added to a route doing 1,000 or more annual treatments, the result is that patients have their treatments postponed or are treated invasively.

This issue is particularly acute in rural areas, where mobile units visit less frequently because of smaller populations. As a result, patients in rural areas may have to wait for two to four weeks to obtain needed lithotripsy services. In such cases, the physician may opt to insert a urethral stent as a temporary measure until the lithotripsy machine becomes available at that rural site. Alternatively, the urologist may perform a more invasive procedure, resulting in

greater risk to the patient. A CON adjustment factor applied to the need and volumes in rural areas would help to address the rural access issue and would make the CON Standards more responsive to the needs of residents of rural Michigan.

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

Likewise, the volume requirements imposed by CON make no allowances for unplanned downtime events and make no provisions for the mobile provider to utilize temporary equipment while necessary repairs are made in order for the approved machine to become operational again. Many situations require replacement parts to be shipped, which can result in an extended period of time during which the service is unavailable. On very busy mobile routes serving multiple rural sites on a very infrequent basis, unavailability of the mobile unit for a week or more can result in long delays for patients requiring lithotripsy or substitution of more invasive, higher risk surgical procedures. A provision under CON for the use of a temporary lithotripsy unit during downtimes for repairs, without having to apply for an emergency CON, would also help to address this concern.

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. Furthermore, a rural adjustment factor of two (2) should be applied to rural host sites, both those currently providing lithotripsy and those applying to initiate the service.

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 are willing to participate in this process as appropriate.

Sincerely,

Ann Stevens, RN
Vice President - Operations
Greater Michigan Lithotripsy

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Testimony
Blue Cross Blue Shield of Michigan/Blue Care Network
CON Public Hearing
October 20, 2009

Thank you for the opportunity to provide testimony on behalf of Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network (BCN). BCBSM and BCN continue to support and actively participate with the Certificate of Need (CON) program. This program has become increasingly significant based on its design to ensure the delivery of cost-effective, high quality health care to Michigan residents.

BCBSM/BCN Recommendations Regarding Standards for Review during 2010

- Neonatal Intensive Care Services/Beds (NICU): The decrease in population and births in Michigan raises the question whether there is overcapacity of NICU in the state. BCBSM/BCN recommends that the CON Commission convene a SAC to evaluate these standards and assess whether or not over-capacity exists in the state, and if so, what can be done to ensure that additional NICU services/beds are not added to the current supply.

- Nursing Home and Hospital Long-Term-Care Unit/Beds: Feedback from the Nursing Home/Long Term Care community (providers and consumers) demonstrates much interest in modifying these standards. Based on our position of supporting open discussion, BCBSM/BCN supports these stakeholders in this effort and if desired by this group, supports the CON Commission in convening a SAC to review these standards.

- CT Scanner Services: BCBSM and BCN have concerns based on the proliferation of numbers, types and locations of CT units and escalating utilization volumes. BCBSM/BCN, thus, recommends that CT Scanner Services CON standards be thoroughly evaluated, and the CON Commission convenes a SAC to do so.

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CON Commission Actions

Proposed MRI CON Standards

BCBSM and BCN support the final action on the MRI simulation language but do not support the final ER language or the charity care provisions still being discussed:

- BCBSM supports the (final) language that exempts MRI units used to simulate megavoltage radiation treatment for cancer. Our clinical group, the BCBSM/BCN collaborative, believes that this is an important component of effective treatment by allowing for more accurate treatment planning, thus yielding higher quality services for patients
- BCBSM and BCN do not support the (final) language that allows replacement of a mobile MRI with a fixed MRI for any hospital emergency room with more than 20,000 visits per year. Based on the input of the BCBSM/BCN clinical collaborative, we feel that there is no public policy rationale for this approach as the majority of MRI services do not need to be completed immediately upon arrival in the emergency department, and in those case where a scan is able to be performed immediately, may be no capacity at such facilities to treat the findings of a positive MRI.

- BCBSM and BCN do not support the concept of replacing mobile MRI units with fixed MRI units for freestanding for-profit imaging centers that provide at least 25% of their service to Medicaid–covered patients. Many questions remain regarding the validity of this proposal from a public policy rationale. Specifically, this additional capacity would be in direct competition with existing hospital-based not-for-profit MRI units, including patients with other types of coverage than Medicaid.

Conclusion

BCBSM and BCN continue to support the CON program and the ongoing review of the standards in terms of cost, quality and/or access concerns. We applaud the CON Commission and MDCH staff as they continue to facilitate an objective review process, by eliciting in-depth clinical expertise as well as input from consumers, purchasers, and payors. BCBSM and BCN will continue to be an open-minded, active participant in these endeavors. As always, BCBSM/BCN commends the CON Commissioners and MDCH staff for their diligent efforts in maintaining CON as a strong, vibrant program to help ensure the delivery of high quality, safe and effective care to patients across the state.

10/19/09

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Public Testimony
Certificate of Need (CoN) Review Standards for Computed Tomography Scanner Services
October 20, 2009

My name is Steven Szelag and I am a Strategic Planner at the University of Michigan Health System (UMHS). UMHS wishes to take this opportunity today to offer comments pertaining to the Certificate of Need (CoN) review standards for Computed Tomography (CT) Scanner Services.

UMHS supports the overall regulations for this service; however, there are several points that need to be addressed:

1. Definition of a CT scanner – The existing definition currently exempts CT scanners used in conjunction with several select modalities such as Linear Accelerators. UMHS believes CT scanners and other imaging modalities, when used in a subsidiary capacity, with any therapeutic and/or diagnostic modality should be exempted from volume driven methodologies. These technologies are evolving into what is termed "fusion imaging" – the combination of more than one modality into a single machine.

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

3. UMHS believes the Department should investigate a "system view" of imaging asset deployment. Healthcare delivery systems with multiple licensed and/or unlicensed medical facilities, under common ownership, require flexibility to improve "point-of-service" care based on changing demographics and demand. The existing CoN Standards for Replacement and Relocation are somewhat restrictive and may not adequately meet the specific needs of the applicant. Regulations currently exist for the movement of licensed medical/surgical beds between multiple licensed facilities under common ownership. Similar regulations for other CoN Covered Services would significantly improve access to healthcare.

4. More consistency is needed between the definitions contained within the CoN Standards and with the definitions contained within the Public Health Code. For example, in definition “a” contained within the CoN Standards for CT Services; initiation means a site that does not perform CT scans as of the date an application is submitted. However, in definition “b” contained within the Public Health Code; initiation means a site that has not offered the service within 12-months of a new service being initiated. The problem here is the Public Health Code definition “trumps” the CoN Standards definition, but the Public Health Code language is contained within a separate document.

    a. CoN Standards: "Initiate a CT scanner service" means to begin operation of a CT scanner, whether fixed or mobile, at a site that does not perform CT scans as of the date an application is submitted to the Department. The term does not include the acquisition or relocation of an existing CT scanner service or the renewal of a lease.
    b. Public Health Code: “Initiate” means the offering of a covered clinical service that has not been offered in compliance with this part or former part 221 on a regular basis at that location within the 12-month period immediately preceding the date the covered clinical service will be offered.

    In this situation UMHS is not requesting that the Public Health Code definition be modified, but rather be more representative in the CoN Standards.

Thank you for according us the opportunity to make this statement today.

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Conclusion

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Public Testimony
Certificate of Need (CoN) Review Standards for Air Ambulance Services
October 20, 2009

My name is Steven Szelag and I am a Strategic Planner at the University of Michigan Health System (UMHS). UMHS wishes to take this opportunity today to offer comments pertaining to the Certificate of Need (CoN) review standards for Air Ambulance Services. These specific comments relate to revisions that were first proposed in 2007. The CoN Commission was unable to take action on these proposed changes due to a pending legal opinion from the Attorney General's office.

Definitions

Section 2 (1)(E), Air Ambulance Service: It is recommend that the entire sentence that reads, "The service shall be capable of providing at least advanced life support services but may include the provision of critical care or specialty care support services", should not be deleted from the proposed revisions.

Section 2 (1)(S), Initiate Air Ambulance Service: It is recommended that reference to "Department Inventory of Air Ambulances" be removed, or Appendix A, which had been deleted from page 11 of the standards, be added back.

Section 2 (1)(Y), Organ Transplant: It is recommended that the definition of Organ Transport includes both the organ and surgical transplant team. There are occasions when the helicopter may be used solely for timely transport of an organ, as in the case of heart or lung transplant. The team will not necessarily accompany the organ. Additionally, there are times when the helicopter may be harvesting an organ outside of Michigan, so the last three words "occurring in Michigan" should be deleted. Therefore, the definition should be modified to read "Organ transport means the use of an air ambulance to transport an organ(s) AND/OR a surgical transplant team between hospitals for transplantation purposes.

Expansion of Air Ambulance Service

Section 4 (1), Expansion: It is recommended that when expanding an air ambulance service the minimum number of patient transports per aircraft is increased to 300. The proposed expansion criteria, agreed upon by the Informal Workgroup, require an existing Air Ambulance service to meet only the minimum volume required for initiation, 275

patient transports per aircraft per year, although the requirement for patient transports and organ transports, combined, is 600 per aircraft per year. It is reasonable to expect that an air ambulance service wishing to expand should perform more than the absolute minimum volume. At least half of the applicant's total air ambulance utilization must be patient transports. This formula of at least half of the applicant's total air ambulance utilization would also be used for an applicant's future expansion to 3 or 4 helicopters.

Section 4(3), Base of Operations: Under the existing Standards for Air Ambulance, the "Base of Operations" is defined as a hospital. The proposed revisions define the base of operations as the place where the aircraft and crew are stationed; in other words, the location of the hangar. The proposed Standards also specify that, when expanding, an air ambulance service must utilize a base of operations for the additional aircraft that is covered by the same Medical Control Authority as the original base of operations. It is likely that an air ambulance service applying to add a helicopter may decide to locate it in a different "base of operations," in order to maintain closer proximity to a larger portion of the community to be served by the service. In many cases, logical secondary sites will be covered by a different Medical Control Authority than the primary site. As a result, the expansion requirements related to the base of operations should be revised. To be approved, the applicant must demonstrate both of the following:

1. Provide a letter of support from the Medical Control Authority for the proposed new base of operation indicating that the applicant's protocols comply with the requirements of the Medical Control Authority.

2. Demonstrate that all existing air ambulance services in the State have been notified of the applicant's intent to expand the air ambulance service to an additional base of operation, by means of certified mail return receipt date before the deemed complete date of the application.

In addition to these proposed changes, UMHS believes the Department should investigate the need for limiting the number the Air Ambulance services in the Lower Peninsula of Michigan. This area of the State has complete Air Ambulance coverage and any incremental services may have negative impacts on cost, quality and safety.

Thank you for according us the opportunity to make this statement today.

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October 27, 2009

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

Dear Mr. Goldman,

This letter is written as formal testimony about the CON Review Standards for Air Ambulance Services which went into effect June 4, 2004.

As a result of comments made relative to these Standards in 2007, substantial changes were made. However, final approval of those changes was withheld, pending an opinion from the Attorney General. Until the legal issues are resolved and the previously revised Standards are put into effect, it does not make sense to make further modifications to the CON Review Standards for Air Ambulance Services. Therefore, Spectrum Health recommends that no changes be made to the CON Standards for Air Ambulance Services at this time.

Spectrum Health appreciates the opportunity to comment on these Standards.

Sincerely,

Robert A. Meeker

Strategic Program Manager

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Public Testimony
Certificate of Need (CoN) Review Standards for Neonatal Intensive Care Unit
October 20, 2009

My name is Steven Szelag and I am a Strategic Planner at the University of Michigan Health System (UMHS). UMHS wishes to take this opportunity today to offer comments pertaining to the Certificate of Need (CON) review standards for Neonatal Intensive Care Unit (NICU) Beds.

UMHS supports the overall regulations for this service; however, a revision to Section 5(2)(c) should be considered. This subsection allows for the expansion of up to 5 incremental NICU beds. An applicant may demonstrate a need for more than 5 beds, based on a NICU bed need formula, but may not be approved for anything greater due to a cap. This restriction could adversely affect an applicant's ability to provide appropriate access even when need is demonstrated. UMHS requests that the Department evaluate and consider revising the cap methodology for determining incremental NICU beds.

Thank you for according us the opportunity to make this statement today.