Blue Cross
Blue Shield
of Michigan

600 E. Lafayette Blvd.
Detroit, MI 48226-2998

Lansing Office
232 S. Capitol Ave. MC L10A
Lansing, MI 48933-1504

October 19, 2018

Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
333 S. Grand Avenue
Lansing, MI 48933

Dear Certificate of Need Commission:

Blue Cross Blue Shield of Michigan appreciates the opportunity to offer comments on the Certificate of Need review standards for air ambulance services up for review in 2019. **Blue Cross supports the continued regulation of air ambulance services**, which is especially important considering the increased cost of air ambulance transports both in this state and nationally.

Air ambulance is a valued service for Michigan's residents to receive timely, quality care for critical injuries. Unfortunately, with increasing frequency, some patients are hit with surprise balance bills that can range in the tens of thousands of dollars, even after the air ambulance provider has accepted the health plan's payment. Blue Cross provides its members with coverage for both emergent and non-emergent medically necessary air ambulance transports, and has done its part to secure contracts or agreements with Michigan's air ambulance providers with generous reimbursement rates. However, when regulation is limited, some for profit air ambulance providers find it favorable to drop out of health plan networks, enabling them to seek increased revenue through unregulated balance billing, and leaving patients vulnerable to unexpected and exorbitant charges.

The CON standards encompass quality assurance and access to care standards that include meeting either national accreditation requirements, or a series of requirements that include patient care protocols, participation in a quality management program, appropriately trained personnel, and procedures to screen patients to ensure appropriate utilization of air ambulance services. The monitoring and reporting requirements of CON play an important role in protecting consumers, in terms of safety of the transport, as well as a mechanism to encourage proper utilization. Air ambulance services are to be provided to all of Michigan's residents based on clinical necessity, and cannot be denied based on payor source. Medicaid participation is required under the CON standards.

Due to the soaring costs of air ambulance services - as just one example, a $13,000 transport in 2007 cost in excess of $50,000 in 2016 - it is important that Michigan retain the ability to regulate what is permissible under the current CON standards. Furthermore, Blue Cross would support strengthening the standards with additional transparency requirements for air ambulance providers to better protect our residents.

Thank you for the opportunity to share our comments. Again, Blue Cross supports the continued regulation of air ambulance services under CON and commends the CON Commission and MDHHS staff for their diligent efforts in maintaining CON as an exemplary state program that helps ensure the delivery of high quality, safe and effective care to patients across the state.

Sincerely,

Mark Cook
Vice President, Government and Regulatory Affairs
Blue Cross Blue Shield of Michigan

Beaumont

October 19, 2018

Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
South Grand Building
333 S. Grand Avenue
Lansing, MI 48933

Re: Air Ambulance Services

Dear Certificate of Need Commission:

Thank you for the opportunity to provide comment on the CON Review Standards up for review in 2019. Beaumont Health supports the continued regulation of Air Ambulance Services. No specific changes to these standards are recommended at this time.

Sincerely,

Patrick O'Donovan
Director, Strategy & Business Development
947-522-1173

AeroMed
SPECTRUM HEALTH

100 Michigan Street NE | MC071
Grand Rapids, MI 49503
616.391.5300
toll free 1.800.862.0921
spectrumhealth.org/aeromed

October 16, 2018

Chairperson James Falahee
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 5th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Dear Chairperson Falahee,

Spectrum Health thanks the CON Commission for the opportunity to provide written testimony on the CON Review Standards for Air Ambulance Services.

Spectrum Health understands that the Emergency Medical Services (EMS) Section within the Department of Health and Human Services has been developing rules pertaining to improving the quality of air ambulance services. We support continued CON regulation under the current standards and project delivery requirements until this process is complete.

Again, thank you for the opportunity to provide feedback on the CON Review Standards for Air Ambulance Services. Spectrum Health appreciates the Commission's consideration of our comments.

Sincerely,

T. Obetts

Tiffany Obetts, RN, BSN

Director, Aero Med & North Flight Aero Med

Beaumont

October 19, 2018

Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
South Grand Building
333 S. Grand Avenue
Lansing, MI 48933

Re: Computed Tomography (CT) Scanner CON Review Standards

Dear Certificate of Need Commission:

Thank you for the opportunity to provide comment on the CON Review Standards up for review in 2019. Beaumont Health supports the continued regulation of Computed Tomography (CT) Scanner Services.

In the current standards under Section 3(2), a hospital that provides 24-hour emergency care services (as authorized by the local medical control authority to receive ambulance runs) is exempt from volume requirements for its first CT scanner. Beaumont recommends that this exemption be extended to 24-hour freestanding 24-hour emergency departments, since CT services must be continuously and immediately available for patients needing emergency treatment.

Sincerely,

Patrick O'Donovan
Director, Strategy & Business Development
947-522-1173

Henry Ford Health System
One Ford Place – Suite 4A
Detroit, MI 48202

October 16, 2018

James Falahee
CON Commission Chairperson
South Grand Building, 4th Floor
333 S. Grand Avenue
Lansing MI 48933

Dear Commissioner Falahee,

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

Henry Ford Health System (HFHS) supports the continued regulation of CT Services and we do not believe there are any necessary changes to the standards as they are currently written. The existing standards are effectively working to control costs, quality and access throughout the state.

Thank you for the opportunity to share our comments.

Respectfully,

Barbara Bressack
Director, Planning and CON Strategy
One Ford Place, 4A
Detroit, MI 48202

SPECTRUM HEALTH

Spectrum Health System

System Government Affairs
648 Monroe Ave NW | MC 065
Grand Rapids, MI 49503

October 18, 2018

Chairperson James Falahee
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 5th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Dear Chairperson Falahee,

Spectrum Health thanks the CON Commission for the opportunity to provide written testimony on the CON Review Standards for Computed Tomography (CT) Scanner Services.

Spectrum Health supports continued CON regulation of this covered service; however, we would like to offer a suggestion for the Commission to consider regarding these standards.

Currently, facilities that rent temporary mobile CT scanners must receive CON approval before one can be used, even if it will only be used while a machine is down for replacement, repairs, or offline during renovations or other unplanned downtimes. Currently, the standards require a non-substantive CON application to be filed and a 45-75 day application review, making it difficult to secure approval for a rental, especially in unplanned events. This adds an undue administrative and financial burden to health systems and negatively affects patient care as the review time often extends beyond the time the unit would have been utilized. Spectrum Health recommends exempting the use of temporary mobile CT scanners when used for less than 90 days.

Again, thank you for the opportunity to provide feedback on the CON Review Standards for Computed Tomography (CT) Scanner Services. Spectrum Health appreciates the Commission's consideration of our comments.

Best regards,

David Walker
Strategic Regulatory Senior Analyst
Spectrum Health System
Government Affairs | MC 065

October 19, 2018

James Falahee
Chair, CON Commission
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Public Comment for Computed Tomography (CT) Scanner Certificate of Need Standards

Dear Chairman Falahee:

Trinity Health Michigan would like to thank the Certificate of Need Commission for the opportunity to comment on the Certificate of Need Review Standards for Computed Tomography (CT) Scanner Services. Trinity Health Michigan supports continued CON regulation of CT Scanner services.

Trinity Health Michigan believes the changes made in 2016 to the Certificate of Need Review Standards for Computed Tomography (CT) Scanners appropriately assure Michigan residents have access to safe, lowest cost, high quality care resources. As such, Trinity Health Michigan does not believe further revisions to these Certificate of Need Review Standards are necessary at this time.

We appreciate the CON Commission's consideration of our comments.

Respectfully,

Robert Casalou
President and CEO, Mercy Health and Saint Joseph Mercy Health System

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

October 19, 2018

James Falahee - CoN Commission Chairperson
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Computed Tomography - Certificate of Need Standards Review

Dear Commissioner Falahee:

This letter is written as formal testimony pertaining to the Certificate of Need (CoN) Review Standards for Computed Tomography (CT) Services. The University of Michigan Health System (UMHS) supports the continued regulation of this covered service; however, UMHS strongly believes a definitional revision is necessary to more accurately classify pediatric patients.

The following narrative is consistent with the attached Magnetic Resonance Imaging (MRI) letter that was provided to the CoN Commission during last year's open comment period for Standards to be reviewed in 2018. This is a point of emphasis as UMHS did not receive a response to this earlier request to review and provide organized guidance for MRI discussion.

Under the current CoN Standards, a Pediatric Patient is defined as any patient less than 18 years of age and a Dedicated Pediatric CT is defined as a fixed CT scanner on which at least 70% of the CT procedures are performed on patients under 18 years of age. UMHS recommends increasing the age limit for pediatric CT studies through 21 years of age (< 22 years of age). This change is necessary to reflect the practice of pediatric medicine in the current era. This change is critical to assure proper health care for the entire "pediatric" patient population.

In 1988 (***Pediatrics*** 1988;81:736), the American Academy of Pediatrics (AAP), the leading professional society in pediatric medicine, redefined the upper limit of age for pediatrics as through age 21 years (up to a patient's 22nd birthday). In 2017, the AAP (Policy Statement: Age Limit of Pediatrics: ***Pediatrics***, September, 2017) has broadened this further by stating that "The establishment of arbitrary age limits on pediatric care by health care providers should be discouraged. Health care insurers and other payers should not place limits that affect a patient's choice of care provider solely on the basis of age." This reflects the common practice of patients with pediatric diseases to be cared for in a pediatric setting often beyond 21 years of age. The United States Food and Drug Administration considers patients to be "pediatric" through age 21 years, defining patients from 18 years to 21 years of age in the "late adolescence" band of pediatrics for classification of study of new drugs and devices (Guidance for Industry and FDA Staff: Pediatric Expertise for Advisory Panels – U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, 2003).

On September 1, 2017 UMHS redefined "pediatric" as including patients up to their 21st birthday. Patients who are 18 to 20 years of age who are new to the system are now preferentially directed to, seen in and cared for within the pediatric hospital and within pediatric clinics. This includes a majority of 18 to 20-year-old emergency room patients. To provide the highest quality, safest and most efficient imaging of these patients, patients 18 to 20 years of age undergo imaging studies in the pediatric environment - this is where the patients are; this is where their doctors are.

This evolution of the definition of the pediatric age range is not unique to UMHS and is occurring at many medical centers throughout the country.

As stated above, the current CT CoN Standards define pediatric as less than 18 years of age. This definition does not align with today's practice of pediatric medicine. Left unchanged this will cause access impediments to CT in a pediatric environment resulting in less than optimal outcomes.

To redefine pediatric as including through age 21 (younger than 22 years of age), this will modernize the guidelines to reflect the current practice of pediatric and young adult medicine and ensure that pediatric patients can obtain imaging with CT proximate within their health care environment, facilitating timely, efficient and high quality health care in patients 18-21 years old.

UMHS urges the CoN Commission to form a Workgroup or Standards Advisory Committee to further evaluate the redefinition of pediatric age limits and develop CoN Standards that appropriately align with this change in care.

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

Respectfully submitted,

T. Anthony Denton, JD, MHA
Senior Vice-President and
Chief Operating Officer
University of Michigan Health System
Michigan Medicine

Paul King, CMPE
Executive Director, C.S. Mott Children's Hospital
and Von Voigtlander Women's Hospital
Michigan Medicine

Peter J. Strouse, MD, FACR
John F. Holt Collegiate Professor of Radiology
Director, Section of Pediatric Radiology
C. S. Mott Children's Hospital
Department of Radiology
Michigan Medicine

Chris J. Dickinson, MD
Chief Clinical Officer, C.S. Mott Children's Hospital
and Von Voightlander Women's Hospital
Professor Pediatric Gastroenterolgy,
Pediatrics and Communicable Diseases
Michigan Medicine

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

October 30, 2017

Suresh Mukherji, MD - CoN Commission Chairperson
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Magnetic Resonance Imaging - Certificate of Need Standards Review

Dear Commissioner Mukherji:

This letter is written as formal testimony pertaining to the Certificate of Need (CoN) Review Standards for Magnetic Resonance Imaging (MRI) Services. The University of Michigan Health System (UMHS) supports the continued regulation of this covered service; however, UMHS strongly believes a definitional revision is necessary to more accurately classify pediatric patients.

Under the current CoN Standards a Dedicated Pediatric MRI is defined as an MRI unit on which at least 80% of the MRI procedures are performed on patients under 18 years of age. Sections 8 (Dedicated Pediatric MRI) and 9 (Hospital Based IMRI) also utilize this same pediatric age cohort as a requirement for approval.

UMHS recommends increasing the age limit for pediatric MRI studies through 21 years of age (< 22 years of age). This change is necessary to reflect the practice of pediatric medicine in the current era. This change is critical to assure proper health care for the entire "pediatric" patient population.

In 1988 (***Pediatrics*** 1988;81:736), the American Academy of Pediatrics (AAP), the leading professional society in pediatric medicine, redefined the upper limit of age for pediatrics as through age 21 years (up to a patient's 22nd birthday). In 2017, the AAP (Policy Statement: Age Limit of Pediatrics: ***Pediatrics***, September, 2017) has broadened this further by stating that "The establishment of arbitrary age limits on pediatric care by health care providers should be discouraged. Health care insurers and other payers should not place limits that affect a patient's choice of care provider solely on the basis of age." This reflects the common practice of patients with pediatric diseases to be cared for in a pediatric setting often beyond 21 years of age. The United States Food and Drug Administration considers patients to be "pediatric" through age 21 years, defining patients from 18 years to 21 years of age in the "late adolescence" band of pediatrics for classification of study of new drugs and devices (Guidance for Industry and FDA Staff: Pediatric Expertise for Advisory Panels – U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, 2003).

On September 1, 2017 UMHS redefined "pediatric" as including patients up to their 21st birthday. Patients who are 18 to 20 years of age who are new to the system are now preferentially directed to, seen in and cared for within the pediatric hospital and within pediatric clinics. This includes a majority of 18 to 20-year-old emergency room patients. To provide the highest quality, safest and

most efficient imaging of these patients, patients 18 to 20 years of age undergo imaging studies in the pediatric environment - this is where the patients are; this is where their doctors are.

This evolution of the definition of the pediatric age range is not unique to UMHS and is occurring at many medical centers throughout the country.

As stated above, the current MRI CoN Standards define pediatric as less than 18 years of age. This definition does not align with today's practice of pediatric medicine. Left unchanged this will cause access impediments to MRI in a pediatric environment resulting in less than optimal outcomes.

To redefine pediatric as including through age 21 (younger than 22 years of age), this will modernize the guidelines to reflect the current practice of pediatric and young adult medicine and ensure that pediatric patients can obtain imaging with MRI proximate within their health care environment, facilitating timely, efficient and high quality health care in patients 18-21 years old.

UMHS urges the CoN Commission to form a Workgroup or Standards Advisory Committee to further evaluate the redefinition of pediatric age limits and develop CoN Standards that appropriately align with this change in care.

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

Respectfully submitted,

T. Anthony Denton, JD, MHA
Senior Vice-President and
Chief Operating Officer
University of Michigan Health System
Michigan Medicine

Paul King, CMPE
Executive Director, C.S. Mott Children's Hospital
and Von Voigtlander Women's Hospital
Michigan Medicine

Peter J. Strouse, MD, FACR
John F. Holt Collegiate Professor of Radiology
Director, Section of Pediatric Radiology
C. S. Mott Children's Hospital
Department of Radiology
Michigan Medicine

Chris J. Dickinson, MD
Chief Clinical Officer, C.S. Mott Children's Hospital
and Von Voightlander Women's Hospital
Professor Pediatric Gastroenterolgy,
Pediatrics and Communicable Diseases
Michigan Medicine

CIENA HEALTHCARE

October 19, 2018

Mr. James Falahee, JD
Chairman
Certificate of Need Commission
Michigan Department of Community Health
333 S. Grand Avenue
Lansing, Michigan 48933

Re: CON Standards for Nursing Home/HLTCU Beds

Dear Chairman Falahee,

Thank you for this opportunity to provide comments regarding the Certificate of Need Review Standards for Nursing Home/HLTCU Beds. We support the continued regulation of nursing home/HLTCU beds under the Certificate of Need program but wanted to share some of our thoughts on improvements that could be made to the Standards to make them more responsive to the needs of Michigan's long-term care residents and aging population.

We support the recommendations being submitted by HCAM and echo their thoughts, particularly regarding finding a way to reduce the CON application fees for lease renewals. We appreciate that the fees are set by the Legislature in statute, but would ask the Commission to consider submitting a request to the Legislature to amend the fees in a way that would recognize the burden these fees place on the facilities and the cost they add to the healthcare system. Perhaps a lower fee structure for non-substantive CON applications could be an appropriate solution.

We also strongly support HCAM's call for a thorough review of the bed need methodology. In a report by Paul Delamater, PhD last year, he indicated that the methodology uses the patient day use rate (PDUR) by age cohort for the entire Michigan population. Because bed need varies by planning area, we can expect the PDUR rate to vary by planning area as well. Perhaps the methodology should calculate the PDUR specific to each planning area and then use the projected population by planning area to calculate the planning area patient days to arrive at the planning area ADC and in turn the bed need for each planning area. We think this may result in more accurate bed need numbers.

The bed need calculated by Dr. Delamater last year projected the bed need for the year 2022. If the calculation shows a bed need in 2022 then providers need time to complete the CON process, obtain CON approval, create space for the additional beds, and bring them online by 2022. This is a very time intensive process and it is important to project far enough ahead to ensure the beds are available when our aging population needs them. It is also vitally important that we come to agreement on a methodology that works well for our State and implement it as soon as possible.

I thank you for your time in considering these comments and look forward to working with the Commission and Department on these improvements.

Respectfully,

David G. Stobb
General Counsel

4000 Town Center ▪ Suite 700 ▪ Southfield, MI 48075 ▪ Phone: (248) 386-0300 ▪ Fax: (248) 386-0314

HCAM CON Concerns for 2019 Standards Review

For Nursing Homes and Hospital Long-Term Care Units

The Health Care Association of Michigan (HCAM) represents over 340 skilled nursing and rehabilitation facilities across the State. HCAM members provide care to some of the most vulnerable elderly and disabled citizens of this State. HCAM continues to support the need for the Certificate of Need process to ensure the values of the system of access, quality and cost are upheld. HCAM went before the CON Commission earlier this year to question the latest bed need calculation and its projected need for more beds. This calculation only highlighted the need to have an extensive review of the bed need methodology reflecting today's health care environment. The bed need review is our top priority and we will work with a Standards Advisory Committee or workgroup whichever is formed by the Commission.

HCAM also has a few other concerns that are listed below along with our priority item. If questions arise please contact Pat Anderson at patanderson@hcam.org or 517-627-1561.

Review of the Bed Need Methodology – Section 3

The November 2017 update to the Nursing Home (NH) and Hospital Long Term Care Unit (HLTCU) Bed Need reports a 7,205 bed need increase over the previous 2015 report—from a need of 39,391 to 46,596, a statewide increase of 18.3 percent in only two years.

Such a dramatic increase in projected need does not appear reasonable. It is inconsistent with occupancy trends, contradicts real life experience of providers, and it does not reflect the rapid changes occurring in the provision of long term care support and services. In addition, the cost implications of adding thousands of nursing home beds in Michigan are significant, as well as the potential negative impact on quality of care for the frail elderly.

Our underlying concern is that the methodology for determining nursing home bed need is not producing results that are consistent with the realities of how people are interacting with this segment of the health care system. This is a concern that has been raised previously. In the fall of 2015, HCAM thought that the projected need was unaccountable *low.* That we now believe the new projection is too *high* merely serves to highlight out concern about the basic methodology that produces such wildly disparate numbers in such a short period of time.

HCAM strongly supports having the CON Commission engage Dr. Paul Delamater and his colleagues to work with all stakeholders to extensively review the current methodology, with a goal of exploring alternatives that reflect the dynamics of long term care support and services in Michigan today.

Requirements for Approval to Renew Existing Leases – Section 9

It is unclear why a renewal of a lease arrangement is included in CON similar to an acquisition of an existing facility that would change key staff. HCAM questions whether the statue provides for a lease to be part of CON. Recommendations below should be considered if new lease or renewal if the parties are the same.

HCAM recommends changes to leases in CON first if they are appropriate and some process changes. We recommend requiring only a waiver be filed when a lease renewal at the existing site which does not involve changes to access or quality. The need to review the renewal of an existing lease seems redundant as the original lease has already been reviewed and approved. HCAM also recommends the application fee be based on the annual value of the leased facility and not the total value of a multi-year lease.

Clarification on Acquisitions and Operating Facility Section 7

Some CON's are issued to a provider who intends to replace a facility that is operating. Due to unforeseen or unplanned circumstances the situation changes and the provider decides to build on the existing site. This may cause the facility to close for a period of time to build the replacement facility. The current standards in Section 7 3 c (iii) sets up the example of an existing facility continuing operation while the replacement is being built and how to handle residents. If the scenario happens that the facility gets a building program agreement with LARA to close then reopen, it is not practicable to track the residents who were displaced. An adjustment or clarification needs to address this issue.

Definitions Section 2

As a general statement when other changes are made to the standards it seems to be a wise idea to review definitions for conformance with the proposed changes. Also sometimes after a change is made and utilized the definition may seem incorrect. For example the replacement beds definition is rather confusing, it word be worthwhile to review it.

Relocation of Nursing Home Beds Section 8

Under this section both donor facility and the receiving facility have to file a CON. Could there be a change to require only the receiving facility to file the CON with an addendum that includes information regarding the donor facility. A donor facility is actually reducing bed capacity and under typical situations bed reductions are not reviewed by CON.

Thank you for the opportunity to comment – Melissa Samuel, HCAM President/CEO.

Oakland Senior Living Operations LLC

October 18, 2018

Mr. James B. Falahee, JD
Chairman, Certificate of Need Commission
Michigan Department of Health and Human Services
333 E. Grand Avenue
Lansing, MI 48933

Dear Chairman Falahee:

I am writing this letter in response to the Commission's request for testimony on changes to the CON Standards for Nursing Home and Hospital Long-Term-Care Unit (HLTCU) Beds.

Many older nursing homes cannot meet current physical plant or equipment standards and cannot correct the deficiencies while still admitting and caring for residents at a level of care and dignity they deserve. In such cases, the existing home must be temporarily shut down or permanently replaced as part of the corrective process. The Michigan Department of Licensing and Regulatory Affairs (LARA) continues the licensed status of nursing homes and nursing home beds that are non-operational or unavailable for occupancy while physical plant or equipment deficiencies are corrected under building program agreements authorized by Section 20144 of the Public Health Code (attached).

The existing Nursing Home Standards, however, may prevent the processing of CON applications required to implement building program agreements because the definition of "existing nursing home beds", and other provisions, may be interpreted to authorize CON applications *only* for homes and beds that are currently operational and available for occupancy. The result is that these CON applications may be rejected as ineligible for CON review.

We respectfully request that the Commission amend the definitions for nursing home beds and other parts of the Standards to make it clearer that existing nursing home beds include nursing homes and nursing home beds that are non-operational or unavailable for occupancy when they are licensed under a building program agreement approved by the Michigan Department of Licensing and Regulatory Affairs (LARA) pursuant to section 20144 of the Public Health Code. Some possible amendment language is attached for your consideration.

Very truly yours,

Lorenzo Cavaliere
Authorized Representative

30078 Schoenherr • Suite 300 • Warren, Michigan 48088

586.563.1500 (O) • 586.563.1200 (F)

PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

333.20144 Licensing on basis of approved building program.

Sec. 20144. A health facility or agency not meeting statutory and regulatory requirements for its physical plant and equipment may be licensed by the department on the basis of a building program approved by the department which:

(a) Sets forth a plan and timetable for correction of physical plant or equipment deficiencies and items of noncompliance.

(b) Includes documented evidence of the availability and commitment of money for carrying out the approved building program.

(c) Includes other documentation the department reasonably requires to assure compliance with the plan and timetable.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

CON Standards for Nursing Home and Hospital Long-Term-Care Unit (HLTCU) Beds.

PROPOSED AMENDMENTS

(PROPOSED CHANGES ARE SHOWN IN BOLD)

1. Sec. 2(1)(a) "Acquisition of an existing nursing home/HLTCU" means the issuance of a new nursing home/HLTCU license as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of ~~**an existing**~~ **A** licensed ~~**and operating**~~ nursing home/HLTCU and which does not involve a change in bed capacity of that health facility. **THE TERM "EXISTING NURSING HOME/HTLCU" SHALL INCLUDE A LICENSED NURSING HOME/ HTLCU THAT IS NOT IN OPERATION OR UNAVAILABLE FOR OCCUPANCY WHILE PHYSICAL PLANT OR EQUIPMENT DEFICIENCIES ARE CORRECTED UNDER A BUILDING PROGRAM AGREEMENT AUTHORIZED BY SECTION 20144 OF THE PUBLIC HEALTH CODE, BEING SECTION 333.20144 OF THE MICHIGAN COMPILED LAWS.**

2. Sec. 2(1)(l) "Existing nursing home beds" means, for a specific planning area, the total of all nursing home beds located within the planning area including: (i) licensed nursing home beds, **INCLUDING LICENSED NURSING HOME BEDS THAT ARE NOT IN OPERATION OR UNAVAILABLE FOR OCCUPANCY WHILE PHYSICAL PLANT OR EQUIPMENT DEFICIENCIES ARE CORRECTED UNDER A BUILDING PROGRAM AGREEMENT AUTHORIZED BY SECTION 20144 OF THE PUBLIC HEALTH CODE, BEING SECTION 333.20144 OF THE MICHIGAN COMPILED LAWS,** (ii) nursing home beds approved by a valid CON issued under Part 222 of the Code which are not yet licensed, (iii) proposed nursing home beds under appeal from a final Department decision made under Part 222 or pending a hearing from a proposed decision issued under Part 222 of the Code, and (iv) proposed nursing home beds that are part of a completed application under Part 222 of the Code which is pending final Department decision. (a) Nursing home beds approved from the statewide pool are excluded; and (b) short-term nursing care program beds approved pursuant to Section 22210 of the Code, being Section 333.22210 of the Michigan Compiled Laws, are excluded.

3. Sec. 2(1)(s) "Nursing home" means a nursing care facility, including a county medical care facility, but excluding a hospital or a facility created by Act No. 152 of the Public Acts of 1885, as amended, being sections 36.1 to 36.12 of the Michigan Compiled Laws, that provides organized nursing care and medical treatment to seven (7) or more unrelated individuals suffering or recovering from illness, injury, or infirmity. This term **INCLUDES A LICENSED NURSING HOME THAT IS NOT IN OPERATION OR UNAVAILABLE FOR OCCUPANCY WHILE PHYSICAL PLANT OR EQUIPMENT DEFICIENCIES ARE CORRECTED UNDER A BUILDING PROGRAM AGREEMENT AUTHORIZED BY SECTION 20144 OF THE PUBLIC HEALTH CODE, BEING SECTION 333.20144 OF**

THE MICHIGAN COMPILED LAWS. THIS TERM applies to the licensee only and not the real property owner if different than the licensee.

4. Sec. 2(1)(t) "Nursing home bed" means a bed in a health facility licensed under Part 217 of the Code or a licensed bed in a hospital long-term-care unit, **INCLUDING LICENSED NURSING HOME BEDS THAT ARE NOT IN OPERATION OR UNAVAILABLE FOR OCCUPANCY WHILE PHYSICAL PLANT OR EQUIPMENT DEFICIENCIES ARE CORRECTED UNDER A BUILDING PROGRAM AGREEMENT AUTHORIZED BY SECTION 20144 OF THE PUBLIC HEALTH CODE, BEING SECTION 333.20144 OF THE MICHIGAN COMPILED LAWS**. The term does not include short-term nursing care program beds approved pursuant to Section 22210 of the Code being Section 333.22210 of the Michigan Compiled Laws or beds in health facilities listed in Section 22205(2) of the Code, being Section 333.22205(2) of the Michigan Compiled Laws.

5. Sec. 2(1)(aa) "Replacement bed" means a change in the location of the licensed nursing home/HLTCU, the replacement of a portion of the licensed beds at the same licensed site, or the replacement of a portion of the licensed beds pursuant to the new model design. The nursing home/HLTCU beds will be in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, etc.) within the replacement zone. **THE TERM INCLUDES LICENSED NURSING HOMES AND NURSING HOME BEDS THAT ARE NOT IN OPERATION OR UNAVAILABLE FOR OCCUPANCY WHILE PHYSICAL PLANT OR EQUIPMENT DEFICIENCIES ARE CORRECTED UNDER A BUILDING PROGRAM AGREEMENT AUTHORIZED BY SECTION 20144 OF THE PUBLIC HEALTH CODE, BEING SECTION 333.20144 OF THE MICHIGAN COMPILED LAWS.**

Beaumont

October 19, 2018

Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
South Grand Building
333 S. Grand Avenue
Lansing, MI 48933

Re: Neonatal Intensive Care Services/Beds

Dear Certificate of Need Commission:

Thank you for the opportunity to provide comment on the CON Review Standards up for review in 2019. Beaumont Health supports the continued regulation of Neonatal Intensive Care Services/Beds. No specific changes to these standards are recommended at this time.

Sincerely,

Patrick O'Donovan
Director, Strategy & Business Development
947-522-1173

Henry Ford Health System
One Ford Place – Suite 4A
Detroit, MI 48202

October 15, 2018

James Falahee
CON Commission Chairperson
South Grand Building, 4th Floor
333 S. Grand Avenue
Lansing MI 48933

Dear Commissioner Falahee,

At Henry Ford Health System, our philosophy is patients are unique and different. For any patient, standard practice is always the first care approach considered, but there is also a recognition that standard practice may need to be tweaked given the physiology of each patient and how they respond to care. The goal is always to do what's best for the patient and family, providing safe, high quality care in a way that meets the needs of the patients and their families.

In 2018, the Department conducted a statewide compliance review of all NICU and SCN services. The compliance review has prompted our SCN team to take a closer look at the standards and project delivery requirements. The standards are modeled after the AAP Neonatology Level 1, 2, 3 & 4 guidelines. However, we now have a greater appreciation for some of the pitfalls of taking a set of guidelines and turning them into CON rules. By doing so, we have taken something meant to heavily influence treatment and ascribed absolutes and fines when not accomplished, regardless of circumstance. Although Henry Ford Health System supports the continued regulation of SCN services and the guidelines by which they were modeled after, we would propose that the standards be updated to recognize that no guideline can be met 100% of the time when considering the needs and safety of individual patients, and in all of our patient populations, the hopes, desires and the remarkably traumatic aspect of separating parents and babies. More specifically, we propose the following changes:

- Mechanical ventilation: In the current CON standards, ventilation is not to be offered in excess of 24 hours in a level 2 NICU (i.e. SCN). Although we make every effort to transfer babies needing mechanical ventilation beyond 24 hours to a level 1 NICU, transferring babies too early will result in more babies being separated from their parents, and being cared for in a more expensive setting than what is necessary as many babies are able to be successfully weaned from mechanical ventilation between 18 and 24 hours. Once it is clear that the baby will need to be on the ventilator more than 24 hours and needs to be transferred, there are a multitude of factors that can result in the baby needing to stay at the SCN beyond the 24 hours in order to ensure safe transport of the baby to a NICU. We need to remember that the safety of the baby is the highest

priority. Therefore, we would like to suggest that, in recognizing this as a guideline, SCNs should be required to meet this guideline in at least 75% of the babies they care for.

- Total Parenteral Nutrition (TPN): Also modeling the AAP guidelines, the rules require that TPN is to be offered only in a NICU. This standard was developed at a time when TPN required an onsite specially trained pharmacist to prepare the nutrition in an appropriate hood for sterility maintenance. Since this form of nutrition can now be ordered pre-mixed through a manufacturer and delivered to hospitals typically the same day, we believe it would be safe to offer in SCNs that are appropriately staffed by board certified/eligible neonatologists as well as NNPs and Nurses. Some newborns need only TPN and for just a few days to a week. By prohibiting SCNs from providing TPN, these newborns have to be transferred to a level 3 NICU, which adds risks for the baby and interrupts the ability of the family to remain together. Given the ease of obtaining and administering TPN, we'd like to recommend that this capability be added to the SCN definition for any SCN with access to pre-mixed TPN (to specifications). This change in standards will:
    - reduce transfers;
    - reduce the burden of level 3 NICUs to accept more babies (perhaps only to transfer them back as soon as feeds are adequate;
    - provide better opportunity to keep mom and baby together; and
    - allow for TPN to be administered appropriately for more efficient nutrition for the baby.

  The change would ultimately reduce cost and improve safety and outcomes. Importantly, all babies need uninterrupted (and adequate) nutrition for appropriate weight gain and brain growth from placental separation to onset of nutrition after birth. Allowing for TPN to be administered would go a long way in meeting this objective without having to rush to increase PO feeding and face other complications.

We appreciate the opportunity to provide comment and suggestions. And look forward to working with you to improve these standards.

Respectfully,

Dr. Sudhakar Ezhuthachan, MD
Division Head, Neonatology
Henry Ford Health System
2799 W. Grand Blvd
Detroit, MI 48202

SPECTRUM HEALTH
Helen DeVos
children's hospital

October 15, 2018

Neonatal Center | MC035
100 Michigan Street NE
Grand Rapids, MI 49503
616.391.1370 fax 616.391.1332
helendevoschildrens.org

Chairperson James Falahee
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 5th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Dear Chairperson Falahee,

Spectrum Health thanks the CON Commission for the opportunity to provide written testimony on the CON Review Standards for Neonatal Intensive Care Services/Beds and Special Newborn Nursing Services (NICU).

Spectrum Health supports continued CON regulation of this covered service, however we would like to offer two suggestions for the Commission to consider including in the standards.

First, we believe that the definition of "special care nursery services" should be modified to include High Flow Nasal Cannula (HFNC) treatment as an accepted service. Specifically, HFNC should be added to Section 2(v)(v). This will provide clarity on the appropriate use and time of use for respiratory support before a transfer to a higher level of care is necessary. Spectrum Health is concerned that the current standards could create an opportunity for HFNC to be used rather than continuous positive airway pressure and postpone necessary transfers to a higher level of care.

Second, Spectrum Health believes that Neonatal Abstinence Syndrome (NAS) should also be added as a service adequate for special care nursery services (SCN) in Section 2(v). Given the recent opioid epidemic, NAS has become a significant issue for hospitals across the country. There is a concern among neonatologists that newborns with NAS are being transferred to the NICU when these patients can be safely treated in the SCN setting. Treatment in an SCN will allow newborns to receive the treatment they need without having to be transferred to a NICU, where it is possible the closest service is many miles away.

Again, thank you for the opportunity to provide feedback on the CON Review Standards for Neonatal Intensive Care Services/Beds and Special Newborn Nursing Services. Spectrum Health appreciates the Commission's consideration of our comments.

Sincerely,

Edgar Beaumont

Edgar Beaumont, MD
Medical Director, Helen DeVos Children's Hospital Neonatology

October 19, 2018

James Falahee
Chair, CON Commission
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Public Comment for NICU/SCN Certificate of Need Standards

Dear Chairman Falahee:

Trinity Health Michigan would like to thank the Certificate of Need Commission for the opportunity to comment on the Certificate of Need Review Standards for Neonatal Intensive Care Services/Beds and Special Care Nursery Services. Trinity Health Michigan has both level III and level II centers. Trinity Health Michigan supports continued CON regulation of these services but would support a review of what we believe to be significant and clinically important discrepancies between the language in the Michigan CON Standards and the recommendations in the AAP Policy Statement on the Levels of Neonatal Care.

Specifically, Trinity Health Michigan believes the portion of the definition of SCN services in Section 2(1)(v) of the CON Standards that states "….provide mechanical ventilation or CPAP or both for a brief duration (not to exceed 24 hours combined)" is notably different language than the AAP Policy Statement which reads: SCN may "provide mechanical ventilation for brief duration (<24 h) or continuous positive airway pressure or both". The AAP Policy Statement very clearly separates CPAP and mechanical ventilation as two separate modalities. Mechanical ventilation, not CPAP, should be limited to 24 hours. We believe this discrepancy between the CON requirements and the AAP standard of care has the potential to create confusion, and may lead to unnecessary transports that may actually put some babies at increased risk.

Likewise, Trinity Health Michigan believes the current CON standards have not kept up with technological advances that improve access to care, such as the use of telemedicine. The AAP Policy Statement clearly integrates telemedicine as a valuable tool for Level III NICUs in accessing pediatric medical and pediatric surgical subspecialty consultations. We believe the CON standards for NICUs (Section 12(2)(h)) should recognize telemedicine as a part of the Level III NICU toolbox or, minimally, clarify that "on-site physician consultation services" may also be accomplished through telemedicine physician consultation.

Because these issues are clinically complex, we would encourage the CON Commission to establish a Standards Advisory Committee comprised of clinical experts to review the current CON Review Standards and to recommend changes necessary to more clearly align the CON Review Standards for both NICU and SCN services with the requirements outlined in the AAP Policy Statement on the Levels of Neonatal Care.

We appreciate the CON Commission's consideration of our comments.

Respectfully,

Robert Casalou
President and CEO, Mercy Health and Saint Joseph Mercy Health System

UMS®
UNITED MEDICAL SYSTEMS

October 19, 2018

Mr. James Falahee, JD
Chairman
Certificate of Need Commission
Michigan Department of Community Health
333 S. Grand Avenue
Lansing, Michigan 48933

Re: CON Standards for UESWL Services

Dear Chairman Falahee,

Thank you for this opportunity to provide comments regarding the Certificate of Need Standards for Urinary Extracorporeal Shockwave Lithotripsy (UESWL) Services. As the managing partner of Great Lakes Lithotripsy and Michigan CON, LLC, two mobile UESWL providers in Michigan, we wanted to share our thoughts regarding three potential changes to these standards as you prepare for your review of them in the coming year.

As you may recall, fairly significant changes were made to these standards earlier this year. Generally, we wouldn't propose additional changes so soon, but we believe that those prior changes should have resulted in an additional change in the project delivery requirements. More specifically, the CON Commission removed Section 7(4) from the standards which required an existing mobile route proposing to add a host site in a region that they did not currently serve, to project a minimum of 100-lithotripsy procedures per year in that region. The provision was removed in order to allow expansion of geographic access to this service, supporting existing investment to provide even more service across the State. We request that this 100 procedure volume per region be removed from the Project Delivery Requirements in Section 9(4)(a) and any other areas of the standards such as Section 4(3)(c) and Section 7(1)(a).

Requiring 100-procedure minimum volume per region is incentive for mobile routes to drop service at low volume centers in less populated regions. For example, during a recent compliance review, the Department pointed out that a mobile lithotripsy route that was exceeding the minimum volume for the route in total, was providing service in two regions where the total procedures in each region did not meet the 100 minimum. The route is now faced with a few options:

1. Continue to provide service to the regions and face continued fines from the State.
2. Stop providing service to the regions and leave the patients in those areas without service.
3. Move the host site to a different route that provides at least 100 procedures in that region but force them to rearrange their OR schedule to accommodate a change in lithotripsy schedule in order to make this change.

As we have explained in the past, the technologist for the lithotripsy unit travels with the unit across the state, therefore the provision does not promote quality. Rather, it makes it more difficult for CSCs to provide service in less populated areas, potentially limiting access. Some may argue that it could reduce costs by prohibiting a route from traveling to a region that doesn't meet a threshold volume, however the cost savings would pale in comparison to the decrease in access. Additionally, the cost to providers to offer service in these regions is increased by the State fining the CSCs under compliance review. We believe all of these factors support removing this requirement in all sections of these standards.

1700 West Park Drive, Suite 410
Westborough, MA 01581
Phone: 508-870-6565
Fax: 508-870-0682

UMS®
UNITED MEDICAL SYSTEMS

Secondly, we propose a change to the standards that would allow for two existing routes to merge existing units and host sites into a single route. Currently Great Lakes Lithotripsy owns or manages 4 mobile lithotripsy routes that have a combined 7 lithotripsy units providing service across the State. Each route has a very specific list of host sites that are approved to provide service to. While we appreciate that host sites are approved for a specific route and monitored to ensure sites are not receiving service from unapproved routes, we do believe there is great potential for improving efficiencies by allowing multiple routes to merge together into a single route. This would allow more flexibility in scheduling and providing service to host sites in the most efficient manner. For example, Host Site A is approved on Lithotripsy Route #1 and normally receives service on Mondays, but Lithotripsy Route #1 has a maintenance problem and can't provide service that day. Lithotripsy Route #2 (owned by the same CSC as Route #1) has a light Monday with only 2 procedures scheduled first thing in the morning and is available to go to Host Site A in the late morning so that the patients at Host Site A don't have to be rescheduled. But Lithotripsy Route #2 doesn't have CON approval to provide service at Host Site A. By allowing the CSC to obtain CON approval to merge Route #1 and Route #2 together, both units could provide service to Host Site A in the most efficient and effective manner under the circumstances presented. Without adding this provision, the only way to obtain the same outcome is to file CON applications to add every host site to every route. This would require the filing of hundreds of applications and would cost hundreds of thousands of dollars in CON application fees when every applicant already has CON approval to provide lithotripsy services. Additionally, if the host site was not served by both routes within a calendar year the CON to be added to that route would be expired, requiring the Host site to refile a CON application if seeking service from another route in the future. We think a provision added to the acquisition section of the standards allowing for an existing mobile lithotripsy route to acquire another existing lithotripsy route and merge the two together, resulting in a single route with approval to provide service to all host sites approved on both routes at the time of application would be a positive improvement and would be in line with the purpose of Certificate of Need by improving access while reducing costs.

Finally, Section 9(5)(c) of the Project Delivery Requirements requires each mobile lithotripsy service to establish and maintain an Operations Committee to oversee the effective and efficient use of the lithotripsy unit(s). We fully support this requirement and have made our best efforts to comply with it. However, the provision requires membership from each host site served by the route, and that has proven to be overly burdensome to meet. We have over 80 host sites and having an operations committee with over 80 members would not be conducive to efficient operations. We would request this provision be modified to allow some discretion on the part of the mobile routes to ensure adequate representation of host sites while not requiring EVERY host site have membership.

I do appreciate your time in considering these comments and would be happy to participate in any discussions or other activity that the Commission sees fit in further updating these standards.

Respectfully,

Scott Sasserson
President and CEO

1700 West Park Drive, Suite 410
Westborough, MA 01581
Phone: 508-870-6565
Fax: 508-870-0682

Proud recipient of the prestigious Lithotripsy & Laser Healthcare Facilities Accreditation Program Certification

Henry Ford Health System
One Ford Place – Suite 4A
Detroit, MI 48202

October 16, 2018

James Falahee
CON Commission Chairperson
South Grand Building, 4th Floor
333 S. Grand Avenue
Lansing MI 48933

Dear Commissioner Falahee,

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need review standards for Urinary Extracorporeal Shock Wave Lithotripsy Services:

Henry Ford Health System (HFHS) supports the continued regulation of Urinary Extracorporeal Shock Wave Lithotripsy Services and we do not believe there are any necessary changes to the standards as they are currently written. The existing standards are effectively working to control costs, quality and access throughout the state.

Thank you for the opportunity to share our comments.

Respectfully,

Barbara Bressack
Director, Planning and CON Strategy
One Ford Place, 4A
Detroit, MI 48202

MEMORANDUM – PUBLIC COMMENT FOR 2019 UESWL REVIEW STANDARDS

To: MDHHS CON Commission and Department
From: Anne Mitchell, Citizen
RE: Public Comment for 2019 UESWL Review Standards
Date: October 19, 2018

Distinguished Commissioners and Michigan DHHS CON Department:

Thank you for the opportunity to comment on UESWL Review Standards for 2019.

After more than thirty years governing UESWL Services under CON it is no longer responsible to regard methodology for restricting costly UESWL medical services in fundamental principle to merely concern capital expense. More than 33 years ago when the FDA approved UESWL technology after a brief six month evaluation and amidst a dark cloud of controversy nothing even close to adequate understanding of the long term effects of UESWL use were considered before forging ahead to market. The "non-invasive" UESWL sales pitch was to rue the day in critical absence of truthful scientific understanding of ***any*** costly underlying unnecessary adverse effects. To bolster today's prevailing outrageous business schemes and "Fair Market Value" UESWL "arrangements," the **cost** in both life and treasure has become morally repugnant, intellectually dishonest, cruel, absolutely unjustifiable, and indefensible. Intentionally neglecting and ignoring the critical data obvious for life-altering adverse effects that might otherwise have easily been predicted decades ago is today a dishonest and unaccountable means for monitoring any cost, quality, and access measures of harmful medical devices/services. No comparisons have been measured of cost, quality, and access against alternative treatments we know are far safer and more effective – no public health agency seems to care about this profoundly important information. When viewed holistically, the grand cost of UESWL is staggering, the quality poor, and access must be restricted by means of critical oversight of quality measures. Commerce in the form of shady kick-back schemes does not trump human life in the United States, folks.

A comprehensive new report on chronic kidney disease from the University of Virginia's Department of Public Health Sciences in Charlottesville found the condition affects nearly 14 percent of the U.S. population and costs billions in Medicare spending each year. The research which fills two massive volumes was led by Rajesh Balkrishnan, PhD, of UVA. Data in the report were provided by the United States Renal Data System.

Highlighted below are five findings from the report:

1. In 2013, Medicare spending for end-stage renal disease, or kidney failure, rose to $31 billion, not including $50 billion spent on chronic kidney disease among those 65 and older.
2. Medicare Part D patients with chronic kidney disease spent roughly $3,675 in 2013 on prescription drugs, which is 46 percent higher than prescription spending for general Medicare patients ($2,509).
3. Prescription spending for Part D patients with kidney failure was considerably higher still: At $6,673 per patient per year, spending was 2.6 times higher than general Medicare patients. Dialysis patients spent the most, at $7,142 a year.

4. Spending for Part D-covered medications for chronic kidney disease patients who received Medicare's low-income subsidy, at $6,088, was more than twice as high as those who didn't receive the subsidy, at $2,873. Patients who received the subsidy paid 1 to 20 percent in out-of-pocket costs, compared to patients who didn't receive the subsidy and paid 28 percent to 32 percent.
5. More than two-thirds (69.4 percent) of Medicare patients with chronic kidney disease and 74.2 percent of those with kidney failure were enrolled in Medicare Part D.

Please consider the following research by the Swiss:

EXTRACORPOREAL SHOCK-WAVE LITHOTRIPSY (ESWL) FOR RENAL STONES IS ASSOCIATED WITH DECREASED KIDNEY FUNCTION AFTER LONG TERM FOLLOW-UP
Christian Fankhauser, Josias Grogg, Alexander Holenstein, Qing Zhong, Johann Steurer, Thomas Hermanns, Tullio Sulser, Cedric Poyet, Zurich, Switzerland

INTRODUCTION AND OBJECTIVES: Beside well characterized short term adverse effects of extracorporeal shock wave lithotripsy (ESWL) for the treatment of renal stones, concerns regarding long term adverse effects to the kidneys or adjacent organs (e.g. pancreas) were raised. We aimed to analyze whether ESWL applied to the kidneys is associated with decreased kidney function, hypertension or diabetes during long term follow-up.
METHODS: All patients with urolithiasis treated by ESWL at our tertiary care center between 1992 and 2013 were retrospectively identified. Cases consisted of patients treated by ESWL because of kidney stones (kidney group). Patients with distal ureter stones treated by ESWL served as a control group. Patients treated by ESWL for upper or middle ureter stones or patients treated for both, kidney and distal ureter stones were excluded. In 2016, a questionnaire was sent to all patients to assess the prevalence of decreased kidney function, hypertension and diabetes. The Swiss Health Survey data set (n¼21,597) providing population data for hypertension and diabetes but not decreased kidney function was used as an additional comparison group.
RESULTS: Of 7108 identified patients, 2,776 (39%) met the inclusion criteria. Follow-up questionnaires were returned by 764 (28%) patients of which 585 (77%) questionnaires belonged to the kidney group, and 179 (23%) to the distal ureter group. Median time between first ESWL and returned questionnaire was 12 years (8-18 years) for the kidney group and 16 years (IQR 11-20 years) for the control group. There was no significant difference between the kidney group and the control group regarding age (mean 62+-14 vs. 64+-14, p¼0.252), gender (female 34% vs. 28%, p¼0.123) and BMI (mean 26+-4 vs. 26+-4, p¼0.687). However, in the kidney group more number of ESWL sessions were observed compared to the control group (1 [IQR 1-2] vs. 1 [IQR 1-1], p<0.001). Furthermore the prevalence of decreased kidney function in the kidney group was significantly higher compared to the control group (8.3% vs. 2.9%, p¼0.015). The kidney group, control group and general population showed significant differences regarding

prevalence of hypertension (47.5% vs. 49.4% vs. 27.5%, p<0.001) and diabetes (14.1% vs. 11.9% vs. 4.9%, p<0.001). In multivariable regression analyses controlling for age, gender and BMI, number of applied ESWL sessions to the kidneys was an independent predictor for decreased kidney function (OR 1.28, 95% CI 1.010 to 1.623, p¼0.041) but not for hypertension or diabetes.
CONCLUSIONS: ESWL for renal stones may lead to decreased kidney function during long term follow-up. The association between increasing number of applied ESWL sessions and decreased kidney function at long-term follow-up supports a causal relationship.
Source of Funding: none

Switzerland has 8.3 million citizens to our US population of 337 million: They are a mere 2.5 percent of us. Overall disease burden of the Swiss population is 17,749 out of every 100,000 compared to the US' 23,104. The Swiss experience 25% better overall health than we do the United States: This is far beyond statistically significant. Swiss urologists do not receive outlandish secret financial "Fair Market Value" incentives to perform UESWL and are free to report honest scientific findings that concern them. You will never see relevant, critical, truthful findings ever published by American urologists about UESWL: The money is far too powerful a force for there to be candor – the truth of what has been happening here in the USA must remain concealed to protect them in their fearful estimation. Their "Fair Market Value" Safe Harbor has clouded their objectivity and medical judgement; this is costing the American people very dearly. Please consider the variables, here, and do the math. None of this is a joke. All of this can be monitored.

What years of your life are most important? Are they today, or 20 years from now? Are kidney stone patients choosing UESWL treatment unwittingly without knowing they may be forging a life ahead of unnecessarily suffering with CKD or ESRD? Who is paying for all this? Be honest and let this be a time of reckoning. Americans deserve honest, cost-effective, safe, high quality medical care. It might be wise to begin knocking off several of our most costly problems in healthcare by taking a much more thoughtful and relevant look - with kidney disease being one of them. We need to look at "need" far differently when it comes to UESWL. Perhaps we can scale models by State to approximate the more healthy Swiss population.

When we do not stand up for our values in the light, the dark side know they can do bad things and get away with them. This is the time to begin to honor the truth and do the right thing. It would be a disgrace to brush responsibility aside about this UESWL debacle, and not seek the truth of this matter in a way that respects cost, quality, and the access to this harmful and dangerous technology and its benefactors.

I support an expanded explicit CON Standard for UESWL that takes the full facts of cost, quality, and access into account.

Thank you very much.

Sincerely,

Anne Mitchell
Citizen

SPECTRUM HEALTH

Spectrum Health System

System Government Affairs
648 Monroe Ave NW | MC 065
Grand Rapids, MI 49503

October 18, 2018

Chairperson James Falahee
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 5th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Dear Chairperson Falahee,

Spectrum Health thanks the CON Commission for the opportunity to provide written testimony on the CON Review Standards for Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services.

Spectrum Health believes that continued regulation of UESWL Services will serve the citizens of Michigan well. We do not believe that any changes are necessary to the current standards.

We appreciate the Commission's consideration of our comments.

Best regards,

David Walker
Strategic Regulatory Senior Analyst
Spectrum Health System
Government Affairs | MC 065

October 19, 2018

James Falahee
Chair, CON Commission
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Public Comment for Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Certificate of Need Standards

Dear Chairman Falahee:

Trinity Health Michigan would like to thank the Certificate of Need Commission for the opportunity to comment on the Certificate of Need Review Standards for Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services. Trinity Health Michigan supports continued CON regulation of Lithotripsy services.

Trinity Health Michigan believes the review of the Lithotripsy CON Standards, and resulting changes made in 2018, appropriately assure Michigan residents have access to safe, lowest cost, high quality care resources. As such, Trinity Health Michigan does not believe further revisions to these Certificate of Need Review Standards are necessary at this time.

We appreciate the CON Commission's consideration of our comments.

Respectfully,

Robert Casalou
President and CEO, Mercy Health and Saint Joseph Mercy Health System

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

October 19, 2018

James Falahee - CoN Commission Chairperson
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Urinary Extracorporeal Shock Wave Lithotripsy - Certificate of Need Standards Review

Dear Commissioner Falahee:

This letter is written as formal testimony pertaining to the Certificate of Need Review Standards for Urinary Extracorporeal Shock Wave Lithotripsy Services. The University of Michigan Health System supports the continued regulation of this covered service and does not believe any specific revisions to these standards are necessary at this time.

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

Respectfully submitted,

T. Anthony Denton, JD, MHA
Senior Vice-President and
Chief Operating Officer
University of Michigan Health System
Michigan Medicine

Ascension

Ascension Michigan
28000 Dequindre Rd
Warren, MI 48092

ascension.org

October 19, 2018

Chairman James Falahee
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
South Grand Building
333 S. Grand Avenue
Lansing, MI 48933

Via E-Mail: MDHHS-ConWebTeam@michigan.gov

Dear Chairman Falahee:

On behalf of Ascension Michigan please accept this correspondence as formal testimony regarding Ascension Michigan's recommendations on the following CON standards eligible for review in 2019: Air Ambulance Services, CT Scanner Services, NICU and Special Newborn Nursing Services, Nursing Home and HLTCU Beds, and UESWL Services.

Air Ambulance

Ascension Michigan has no recommended changes for CON Air Ambulance standards at this time.

CT Scanner Services

Ascension Michigan recommends reviewing the maintenance volume requirement for existing units.

NICU/SCN Services

Ascension Michigan recommends modifying the language in the definition of Special Care Nursery and in section (9) requiring that the provision of mechanical ventilation or continuous positive airway pressure be no more than 24 hours to language that would provide that this requirement would only have to be met 75% of time. It has been our experience that we may have a baby that is on CPAP that may not be that unstable and may only need a couple hours past the 24-hour mark before coming off CPAP or vent. Rather than transferring to another facility, it would have less impact on the baby and family to have them remain in our care in these circumstances.

Ascension

Ascension Michigan
28000 Dequindre Rd
Warren, MI 48092

ascension.org

Nursing Home and Hospital Long Term Care

Ascension Michigan recommends reviewing whether or not adequate access exists for Medicaid patients and the potential need to expand specialty population beds as the population continues to age.

UESWL Lithotripsy

Ascension Michigan has no recommended changes at this time for this service.

Sincerely,

Sean Gehle
Chief Advocacy Officer, Ascension Michigan

41650 Gardenbrook Road ● Suite 175 ● Novi, MI 48375 ● 248.596.1006 ● www.eamonline.org ● @EAMOnline

October 19, 2018

Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
South Grand Building
333 S. Grand Avenue
Lansing, MI 48933

Dear Certificate of Need Commission:

This letter is written as formal testimony pertaining to the CON Review Standards for Air Ambulance Services, Computed Tomography (CT) Scanner Services, Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services, and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services Standards which are scheduled for review in 2019.

Air Ambulance
The EAM supports the current Air Ambulance Services Standards and believes it helps maintain a good balance of cost, quality and access. Keeping the service as a CON Standard curtails new services from entering the state that may use practices such as balance billing patients when service is out-of-network with the patient's insurance provider, leading to a devasting financial crisis for the patient, family members, and even employers.

Computed Tomography (CT) Scanner Services
The EAM supports the continued regulation of CT Scanner Services and wishes the CON Commission may research the numerous underperforming free-standing facilities. In the Southeast Michigan region, we calculate 66% of free-standing facilities with a fixed scanner are underperforming which raises a concern on whether patients using these facilities are receiving affordable quality of care. With so many underperforming programs there may be an overabundance of access.

Neonatal Intensive Care Services/Beds (NICU)
The EAM hopes the CON Commission investigates the current NICU bed occupancy rates across the state to see if changes are necessary to ensure adequate access. Currently, numerous facilities are reporting over 80% occupancy with a few hospitals reporting over 90% occupancy. It may be beneficial in understanding if there are geographical "access of care" issues and what the trends for NICU usage may be in the future.

Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services Standards
UESWL Services were just reviewed in 2017 with the Commission taking final steps in revising the Standard in 2018. Therefore, we do not believe any additional review is currently necessary.

Sincerely,

Bret Jackson
President, Economic Alliance for Michigan
bretjackson@eamonline.org