MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS)
CERTIFICATE OF NEED (CON) COMMISSION MEETING

Thursday, December 6, 2018

South Grand Building
333 S. Grand Ave
1st Floor, Grand Conference Room
Lansing, MI 48933

APPROVED MINUTES

I. Call to Order & Introductions

Chairperson Falahee called the meeting to order at 9:30 a.m. Chairperson Falahee introduced new Commissioner Melisa (Lisa) Oca.

A. Members Present:

James B. Falahee, Jr., JD, Chairperson
Thomas Mittelbrun, Vice-Chairperson
Denise Brooks-Williams
Lindsey Dood
Debra Guido-Allen, RN
Robert Hughes
Melanie LaLonde
Amy McKenzie, MD
Melisa Oca, MD
Stewart Wang, MD

B. Members Absent:

Tressa Gardner, DO

C. Department of Attorney General Staff:

Carl Hammaker

D. Michigan Department of Health and Human Services Staff Present:

Tulika Bhattacharya
Amber Myers
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Brooks-Williams, seconded by Commissioner Mittlebrun to approve the agenda as presented. Motion carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of September 20, 2018

Motion by Commissioner Mittlebrun, seconded by Commissioner Lalonde to approve the minutes as presented. Motion carried.

V. Psychiatric Beds and Services – Presentation and Draft Language

Ms. Nagle gave an overview of the draft language (Attachment A).

Lee Ann Odom, Beaumont Health provided a presentation (Attachment B).

A. Public Comment

None.

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Mittlebrun, seconded by Commissioner McKenzie to take proposed action on the language (Attachment A) as presented and move forward to Public Hearing and to the Joint Legislative Committee (JLC). Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

VI. Review Draft of CON Commission Biennial Report to JLC

Ms. Rogers gave an overview of the draft report (Attachment C).

Discussion followed.

Motion by Commissioner Dood, seconded by Commissioner Hughes to approve the report (see Attachment C) and move forward to the JLC. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

VII. Megavoltage Radiation Therapy Services/Units Standard Advisory Committee (MRTSAC) Interim Report (Written Only)

Chairperson Falahee mentioned the written report (Attachment D) from Brian Kastner, MD, MRTSAC Chairperson.

VIII. Psychiatric Beds and Services Workgroup Interim Report (Written Only)

Chairperson Falahee mentioned the written report (Attachment E) from Laura Hirshbein, MD, PhD, Psychiatric Beds and Services Workgroup Chairperson.

IX. Legislative Report

None.

X. Administrative Update

A. Planning & Access to Care Section Update

Ms. Nagel provided an update on the BMTSAC.

B. CON Evaluation Section Update

Ms. Bhattacharya provided an update on the following items:

1. Compliance Report (Attachment F)
2. Quarterly Performance Measures (Attachment G)

XI. Legal Activity Report

Mr. Hammaker provided an update on the CON legal activity (Attachment H).

XII. Future Meeting Dates:

January 31, 2019 (Special Commission Meeting), March 21, 2019, June 13, 2019, September 19, 2019, and December 5, 2019

XIII. Public Comment

Jay S. Dworkin, Ph.D., FONAR Corporation (Attachment I)

XIV. Review of Commission Work Plan

Ms. Rogers provided an overview of the changes to the Work Plan including actions taken at today's meeting (Attachment J).

A. Commission Discussion

None.

B. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner Hughes to accept the Work Plan as presented with updates from today's meeting. Motion carried in a vote of 10 - Yes, 0- No, and 0- Abstained.

XV. Adjournment

Motion by Commissioner Guido-Allen, seconded by Commissioner Hughes to adjourn the meeting at 10:56 a.m. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

Proposal to Help Alleviate the Problem of Child/Adolescent Patients

Waiting in Hospital Emergency Rooms for a Psychiatric Bed

CONTEXT

- For over a year and prior to the current Psychiatric Beds and Services Workgroup, Beaumont has been working with a variety of stakeholders to develop a pathway for improved access to inpatient psychiatric services, especially for children and adolescents who come to an acute-care hospital emergency department and urgently need placement in an inpatient psychiatric bed. Too often, admission of these pediatric patients is delayed – sometimes up to 36 hours after the patients arrive at the ER. The factors impacting access to child/adolescent inpatient psychiatric beds in Michigan are complex and include a severe shortage of child/adolescent psychiatrists in our State. Following discussions with State government leaders and others, Beaumont was invited to work with the Department and develop proposed CON language to increase access for placement of pediatric psychiatric patients presenting to acute-care hospital emergency departments. We appreciate the opportunity to present such language today and we thank the Department for their assistance.
- Beaumont commends Dr. Laura Hirshbein on her thoughtful leadership of the current Psychiatric Beds and Services Workgroup. Although time consuming, those discussions have been wide-ranging and helpful in identifying a number of factors impacting access to inpatient psychiatric beds in Michigan. We made a presentation to the Workgroup on this topic that was well received, and it appears other acute care hospital systems are having similar issues with prompt placement of child/adolescent psychiatric patients from their emergency rooms.
- Child/adolescent access represents a narrow component of the broader charge of the Workgroup, but an important one. Although this proposal is being presented on a parallel track with the Workgroup proceedings, numerous stakeholders, including those serving on the Work Group, have identified this issue as an urgent and critical problem. Immediate action by the CON Commission on this limited proposal will lead to improved placement options for child/adolescent psychiatric patients without conflicting with additional recommendations from the Work Group process in 2019, which we all eagerly await.
- While CON cannot address all or even most of the mental health issues facing our State as the need is great and resources are limited, we urge the Commission to move this limited proposal forward now in order to prioritize a reduction in the number of children who must languish in emergency rooms awaiting placement in a psychiatric bed.

NEED

- The National Alliance on Mental Health notes that the lack of adequate mental health providers and beds inundates emergency rooms causing delays in care and negatively impacts the continuity essential for the care and treatment of these patients. It is unconscionable for pediatric psych patients to languish in an acute-care ER or observation bed for 36-48 hours without getting the psychiatric services these patients require. Beaumont operates 8 hospital ERs in Southeast Michigan which in 2017 collectively saw over 650 patients age 14 and under with psychiatric diagnoses. And based on discussion at the Psychiatric Services Workgroup meetings, it appears other acute-care systems are having similar issues with prompt placement of pediatric psych patients.

- Bed availability is not the only barrier to improved child/adolescent inpatient psychiatric unit access. Of equal importance is the lack of child/adolescent psychiatrists and professional support staff necessary for operation of an inpatient child/adolescent program.
- Per Dr. Delamater's Psychiatric Bed Need Methodology report (dated 10/17/18), both child/adolescent days per 10,000 population and child/adolescent unit occupancy rates increased significantly between 2012 and 2017.
- Per the Michigan Psychiatric Admission Denial Database, for the period July-December 2017, children who experienced denials averaged 8.6 denials per denial event, with "at capacity" cited as the most frequent reason for denial.
- The "CARES" Task Force notes that there is a limited number of psychiatrists in Michigan, and increasing the number of psychiatric residencies will help mitigate this shortage. Per the Kaiser Family Foundation (2016), Michigan has only 44% of the psychiatrists needed to serve the population, and over 100 additional psychiatrists are required to meet mental health needs.
- Strategies to address the acute shortage of psychiatrists in Michigan need to be implemented but improvements in physician staffing will not be immediate. An increase in the number of child/adolescent programs over a broad geographic area and without arrangements for shared psychiatric staffing will exacerbate the limited availability of child/adolescent inpatient psychiatric beds by spreading existing professional staffing too thinly. Across the country and in Michigan, hospitals sometimes have to cap child/adolescent admissions due to both staffing and physical capacity.

PROPOSAL

- The proposal presented to the Commission seeks to create a limited "safety valve" option for better integration of inpatient psychiatric care with acute-care emergency departments that have a high number of pediatric visits with a psychiatric diagnosis. The intent is not to disrupt the bed need methodology or other existing mechanisms for development of new child/adolescent inpatient psychiatric services in Michigan but to find a way to better deploy and share existing resources – particularly operational expertise and staff. Accordingly, the proposal allows for a one-time option to relocate up to 20 child/adolescent beds in overbedded planning areas.
- It is critical to include language that links the applicant to an acute-care hospital with a significant number of pediatric ER visits with psychiatric diagnoses and to require the proposed service to accommodate placement of child/adolescent patients from the hospital ER if possible. This option will only be feasible if there is a close relationship between the applicant, the existing child/adolescent service that agrees to collaborate with the proposed service, and the acute-care hospitals experiencing placement issues for pediatric psychiatric patients. The direction of this proposal is consistent with academic literature and advocacy about decreasing the "silo" effect and barriers between and among providers.
- The proposal may result in a modest increase in the number of venues for admission of child/adolescent psychiatric patients, but not spread a very limited number of pediatric psychiatrists over so many new programs that they will be spending more time in their cars traveling from facility to facility and even less time with patients. The proposal also would permit hospital systems to invest in pediatric psychiatric staffing and recruitment because of a relatively sure path forward for development of a 10-20 bed child/adolescent unit to help alleviate placement delays.

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Attachment C

WORKING DRAFT

STATE OF MICHIGAN

RICK SNYDER,
Governor

Michigan Certificate of Need Commission

SOUTH GRAND BUILDING
333 S. GRAND AVE
LANSING, MI 48933
Phone: (517) 335-6708

MEMORANDUM

Date: December 6, 2018

To: Joint Legislative Committee (JLC)

From: Certificate of Need (CON) Commission

RE: Recommendations Pertaining to the CON Program

MCL 333.22215(1)(f) requires the CON Commission, by January 1, 2005, and every 2 years after January 1, 2005, to "*make recommendations to the joint committee regarding statutory changes to improve or eliminate the certificate of need program*." In addition to the responsibility of submitting the 2-year report to the JLC, MCL 333.22215(1)(e) of the CON law requires the Commission to "*Annually assess the operations and effectiveness of the certificate of need program based on periodic reports from the department and other information available to the commission*." This report is intended to fulfill these requirements.

To start, we would like to remind the JLC that the CON Commission is composed of 11 volunteers and oversees 15 covered services. The CON Commissioners receive no compensation for their services, other than reimbursement for travel expenses. The CON Commission meets five times per year and all meetings are held in Lansing. Every CON Commission meeting is open to the public and subject to the Open Meetings Act. Each CON Commission meeting starts with a declaration of conflicts of interests. The Michigan Department of Health and Human Services ("Department") supports the CON Commission and administers the CON program.

The CON Commission respectfully submits the following bi-annual report:

Based on our continuous review of the program, the CON Commission believes and recommends that the program should be fully supported as it is serving a valuable need. In our bi-partisan judgment, we strongly believe the current CON process meets the statutory requirements for the program.

Our review of the program is based on reports provided to the Commission by the Department, which is done at the close of every fiscal year. The FY2017 CON Program Annual Activity Report is being provided along with this Memo in Attachment C. The FY2018 CON Program Annual Activity Report should be available in January 2019 and be available here: https://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5106-126234--,00.html.

In addition to these annual reports, the Department provides quarterly program section performance reports to the Commission. These reports demonstrate the effectiveness of the CON program in processing letters of intent, applications, emergency applications, and amendments, as well as issuing decisions within the specified time frames set forth in the Administrative Rules.

We would like to provide the JLC a summary of our activities and accomplishments since the January 2017 report. In the last two years, the Commission has updated 10 of the 15 Review Standards for covered services, including:

- Cardiac Catheterization,
- Hospital Beds,
- Megavoltage Radiation Therapy,
- Open Heart Surgery Services,
- Positron Emission Tomography (PET) Scanners,
- Surgical Services,
- Bone Marrow Transplant Services,
- Heart/Lung and Liver Transplant Services,
- Magnetic Resonance Imaging (MRI), and
- Psychiatric Beds and Services.

In some instances, technical changes were made to modernize standards and/or remove unnecessary regulation. In other instances, major changes were made to benefit the cost, quality and/or access of healthcare for Michigan citizens.

A summary of the changes that have been put into effect or are being proposed to the CON Review Standards during 2017 and 2018 is included in Attachment A in an overview chart and in greater detail in Attachment B.

All changes to CON standards, both technical and policy, have been made with the multiple opportunities for public input and with the recommendations of subject matter experts. The statutory process for modifying CON standards includes holding a public hearing before the CON Commission takes final action on any standard. The Commission actively seeks input from the public during the CON Commission meetings and always includes opportunities for public comment/hearings prior to any Commission action.

The CON Commission is currently in process seeking recommendations for modifications to three CON review standards. At the time of this report, there is a workgroup reviewing CON Review Standards for Psychiatric Beds and Services, a Standard Advisory Committee is reviewing Megavoltage Radiation Therapy (MRT) Services/Units, and a Standard Advisory Committee is to be seated to review Bone Marrow Transplantation (BMT) Services yet in 2018.

The following review standards will be reviewed in 2019: Air Ambulance Services, Computed Tomography (CT) Scanner Services, Neonatal Intensive Care Services/Beds (NICU), Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups (NH-HLTCU), and Urinary Extracorporeal Shock Wave Lithotripsy Services/Units.

Per our statutory obligation, the CON Commission submits that there are no statutory changes needed to improve the Certificate of Need program at this time.

The CON Commission respectfully makes one recommendation to the Legislature related to the Michigan Mental Health Code. Based on extensive testimony before the Commission, we are well aware of the extreme difficulty with getting patients admitted into psychiatric inpatient care. One of the many issues identified as hindering access to inpatient psychiatric care is that Physician Assistants and Psychiatric Nurse Practitioners have limited roles in inpatient psychiatric care. The idea was presented to the CON Commission that if these providers could have expanded functions, then access to inpatient psychiatric care could be expanded. The scope of practice of these providers are defined by the Michigan Mental Health Code and is, therefore, outside of the statutory purview of the CON Commission. It is the recommendation of the CON Commission that this issue be reviewed legislatively as a potential solution to increasing access to high quality psychiatric care.

The CON Commission appreciates the continuing support of the Governor and the Legislature for the CON program.

Respectfully yours,

James B. Falahee, Jr, JD, Chairperson Tom Mittelbrun III, Vice-Chairperson

c: CON Commission
Nick Lyon, Director, MDHHS
Nancy Vreibel, Chief Deputy Director, MDHHS
Matt Lori, Senior Deputy Director of Policy, Planning and Legislative Services, MDHHS
Karla Ruest, Legislative Affairs Director, MDHHS
Joseph Potchen Division Chief, Corporate Oversight Division, Attorney General's Office
Beth Nagel, Planning Office Division Director, MDHHS
Tulika Bhattacharya, Manager, CON Evaluation Section, MDHHS
Brenda Rogers, Special Assistant to the CON Commission, MDHH

SUMMARY OF CON REVIEW STANDARDS REVISIONS FOR CALENDAR YEARS 2017 AND 2018 - ATTACHMENT A

Year	Standard	Commission Plan for Review	Review Process	Summary of Major Changes Made/Proposed
2017	Cardiac Catheterization	Formed a Standard Advisory Committee	• Standard Advisory Committee held July - December 2017 • CON Commission took Proposed Action at March 27, 2018 meeting • Public Hearing Held April 26, 2018 • CON Commission took Proposed Action at June 14, 2018 meeting • Public Hearing Held July 19,2018 • CON Commission took Final Action at September 20, 2018 meeting	• Pacemakers and implantable cardioconverter defibrillators can only be performed in licensed hospitals with diagnostic CC CON approval • Replacement language added • Per physician volumes clarified • Definitions updated throughout
2017	Hospital Beds	Formed a Standard Advisory Committee	• Standard Advisory Committee held July - December 2017 • CON Commission took Proposed Action at March 27, 2018 meeting • Public Hearing Held April 26, 2018 • CON Commission took Final Action at June 14, 2018 meeting	• Added Inpatient Rehabilitation Facility Beds Initiation & Replacement requirements • Removed unnecessary regulatory requirements regarding relocating beds • Comparative review requirements modernized • Renewal of lease requirements added
2017	Megavoltage Radiation Therapy	2017: No changes necessary, review in 2020 2018: Formed a Standard Advisory Committee for changes identified	• Standard Advisory Committee held June 2018 -	• Volume requirements and procedure weights are being reviewed by the Standard Advisory Committee
2017	Open Heart Surgery Services	Language dependent upon Cardiac Catheterization Standard Advisory Committee	• CON Commission took Proposed Action at March 27, 2018 meeting • Public Hearing Held April 26, 2018 • CON Commission took Proposed Action at June 14, 2018 meeting • Public Hearing Held July 19,2018 • CON Commission took Final Action at September 20, 2018 meeting	• Adds requirements for replacing an Open Heart Surgery Service
2017	PET Scanners	No changes necessary, review in 2020		
2017	Surgical Services	Department to draft language based on public testimony	• CON Commission took Proposed Action at the June 5, 2017 meeting • Public Hearing held August 3, 2017 • CON Comission took Final Action at September 21, 2017 meeting	• Clarifies requirements for freestanding surgical centers

SUMMARY OF CON REVIEW STANDARDS REVISIONS FOR CALENDAR YEARS 2017 AND 2018 - ATTACHMENT A

Year	Standard	Commission Plan for Review	Review Process	Summary of Major Changes Made/Proposed
2018	Bone Marrow Transplant Services	From a Standard Advisory Committee		• This Standard Advisory Committee is charged to determine if cellular therapies should be considered for regulation under CON or not
2018	Heart/Lung Liver Transplant	No changes necessary, review in 2021		
2018	MRI	No changes necessary, review in 2021		
2018	Psychiatric Beds and Services	Form a workgroup		• This workgroup is charged with reviewing the CON methodology for determining inpatient psychiatric bed need and reviewing if there are any appropriate ways to increase flexibility in transfering or creating units with existing child/adolescent and adult beds.

DETAILED CON REVISIONS FOR FY17 AND FY18 – ATTACHMENT B

During FY2017, the CON Commission revised the review standards for Computed Tomography (CT) Services, Magnetic Resonance Imaging (MRI) Services, Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services, Nursing Home and Hospital Long-Term Care Unit (NH-HLTCU) Beds and Addendum for Special Population Groups, and Psychiatric Beds and Services.

The following list of changes shows new language inserted into the standards in all upper case.

CT Services: The revisions to the CON Review Standards for CT Services include the following and became effective on December 9, 2016.

- Section 2: Definitions removed and updated to de-regulate dental CT scanners used by dentists in the practice of dentistry. This is intended to provide better access to the consumer and more flexibility to the provider in their practice as well as decrease costs. The following definition has been modified as shown:
    - "CT scanner" means x-ray CT scanning systems capable of performing CT scans of the head, other body parts, or full body patient procedures including Positron Emission Tomography (PET)/CT scanner hybrids if used for CT only procedures. The term does not include emission computed tomographic systems utilizing internally administered single photon gamma ray emitters, positron annihilation CT systems, magnetic resonance, ultrasound computed tomographic systems, CT simulators used solely for treatment planning purposes in conjunction with an MRT unit, and non-diagnostic, intra-operative guidance tomographic units, AND DENTAL CT SCANNERS THAT generate a peak power of 5 kilowatts or less as certified by the manufacturer AND ARE specifically designed to generate CT images to facilitate dental procedures BY A LICENSED DENTIST UNDER THE PRACTICE OF DENTISTRY.
- Section 3: Removed reference to dental CT as it's no longer.
- Old Section 4: Removed as it's no longer needed due to deregulation of dental CT.
- New Section 4: Removed reference to dental CT as it's no longer needed.
- Old Section 6: Removed as it's no longer needed due to deregulation of dental CT.
- New Section 5: Removed reference to dental CT as it's no longer needed.
- New Section 7(2): This was changed to waive a requirement for a CT Scanner to operate for 36-month and volume requirement before being replaced if specific criteria has been met. Reduced regulation allows for facilities to more easily replace an existing fixed CT scanner service to a new location in certain situations that are unforeseen to the applicant (same as MRI language), which is intended to decrease costs and increase quality while maintaining access. The specific criteria to waive this requirement are listed below:
    - (ii) THE OWNER OF THE BUILDING WHERE THE SITE IS LOCATED HAS INCURRED A FILING FOR BANKRUPTCY UNDER CHAPTER SEVEN (7) WITHIN THE LAST THREE YEARS;
    - (iii) THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL; OR
    - (iv) THE CT SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF AN ENTIRE HOSPITAL TO A NEW GEOGRAPHIC SITE AND HAS ONLY ONE (1) CT UNIT.

DETAILED CON REVISIONS FOR FY17 AND FY18 – ATTACHMENT B

- Old Section 8: Removed as it's no longer needed due to deregulation of dental CT scanners.
- New Section 9: Modified to allow for the acquisition of a fixed or mobile CT scanner service not meeting volume requirements by an entity if the CT scanner service is 1) owned by the applicant, 2) is under common control by the applicant, or 3) has a common parent as the applicant. The acquisition of a CT scanner service does not change the location of the service. The service would have to meet all other applicable CT standards and project delivery requirements. Reduced regulation allows for facilities to more easily realign their assets when part of a larger health system (same as MRI language), which is intended to decrease costs while maintaining access.
- Old Section 10: Removed as it's no longer needed due to deregulation of dental CT scanners.
- Old Section 12: Removed as it's no longer needed due to deregulation of dental CT scanners.
- Old Section 17: Removed as it's no longer needed due to deregulation of dental CT scanners.
- New Section 14(2)(c): Modified - Through the CON Annual Survey, freestanding facilities are stating that they can't meet this because they are not open 24 hours. This is a requirement that goes back to the 1980's and the Planning Policies. At the time, only hospitals were eligible to provide CT services. Freestanding facilities were added in 1990, and this requirement was maintained. Striking "on a 24-hour basis," still ensures that there is a physician available to make the final interpretation and makes it easier for all facilities to comply with making it more of a technical edit for clarity.
- New Section 20(2)(f): Through the CON Annual Survey, freestanding facilities are stating that they can't meet this because they are not open 24 hours. Again, this is a requirement that goes back to the 1980's and the Planning Policies. At the time, only hospitals were eligible to provide CT services. Freestanding facilities were added in 1990, and this requirement was maintained. This is a technical clarification ensuring that the appropriate facilities are complying with the requirement to maintain access and quality while reducing costs.
- Old Section 20(5) & (6): Removed as it's no longer needed due to deregulation of dental CT scanners.
- New Section 22: Removed reference to dental CT as it's no longer needed.
- New Section 23(2): Removed reference to dental CT as it's no longer needed.
- Other technical edits.

MRI Services: The revisions to the CON Review Standards for MRI Services include the following and became effective on October 21, 2016:

- Section 6 has been modified to allow for the acquisition of a fixed or mobile MRI service not meeting volume requirements by an entity if the MRI service is 1) owned by the applicant, 2) is under common control by the applicant, or 3) has a common parent as the applicant. The acquisition of an MRI service does not change the location of the service. The service would have to meet all other applicable MRI standards and project delivery requirements. Reduced regulation allows for facilities to more easily realign their assets when part of a larger health system, which is intended to decrease costs while maintaining access and quality.
- Other technical edits.

DETAILED CON REVISIONS FOR FY17 AND FY18 – ATTACHMENT B

NICU and Special Newborn Nursing Services: The revisions to the CON Review Standards for NICU and Special Newborn Nursing Services include the following and have been implemented:

- Section 2(1)(v): Definition for "special care nursery services" or "SCN services" has been modified for clarity and what types of services are provided in SCNs. This is a technical edit that does not make any programmatic changes in CON regulation.
- Section 2(1)(w): Added a definition for "well newborn nursery services" and clarifying that well newborn nurseries do not require a CON. This is a technical edit that does not make any programmatic changes in CON regulation.
    - (w) "WELL NEWBORN NURSERY SERVICES" MEANS PROVIDING THE FOLLOWING SERVICES AND DOES NOT REQUIRE A CERTIFICATE OF NEED:
      (i) THE CAPABILITY TO PERFORM NEONATAL RESUSCITATION AT EVERY DELIVERY;

      (ii) EVALUATE AND PROVIDE POSTNATAL CARE FOR STABLE TERM NEWBORN INFANTS;

      (iii) STABILIZE AND PROVIDE CARE FOR INFANTS BORN AT 35 TO 37 WEEKS' GESTATION WHO REMAIN PHYSIOLOGICALLY STABLE; AND

      (iv) STABILIZE NEWBORN INFANTS WHO ARE ILL AND THOSE BORN LESS THAN 35 WEEKS OF GESTATION UNTIL THEY CAN BE TRANSFERRED TO A HIGHER LEVEL OF CARE FACILITY.
- Section 7(2)(c): Eliminated the language that limits the expansion of beds to no more than five. The current standard limits the expansion to no more than 5 beds even if the methodology calculation is higher. There is no need for this cap, and this change is meant to improve access to care.
- Other technical edits.

Psychiatric Beds and Services: The revisions to the CON Review Standards for Psychiatric Beds and Services include the following and became effective on December 9, 2016:

- To improve access to high quality psychiatric care, the Psychiatric Beds and Services standards were updated with an addendum that creates extra psychiatric inpatient beds to specifically care for three statewide special population groups: developmentally disabled; geriatric and medical psychiatric care. This update created 170 psychiatric inpatient beds of which 150 were for adults and 20 were for child/adolescent care.
- Section 2: Definition has been modified as follows:
    - "Comparative group" means the applications which have been grouped for the same type of project in the same planning area OR STATEWIDE SPECIAL POPULATION GROUP and are being reviewed comparatively in accordance with the CON rules. Definition updated to include special population groups covered under the new addendum, which is intended to provide additional access.
- Section 15(1)(d): Modified to provide more flexibility to the provider, which is intended to positively impact patient access. Insertions show as follows:
    - There shall be the following minimum staff employed either on a full-time basis or ACCESS TO on a consulting basis AS NEEDED.
- Addendum for Special Population Groups has been added for specific needs, i.e., developmentally disabled, geriatrics, and medical psychiatric. The addendum sets

criteria for initiating beds for the specific special population groups as well as project delivery requirements that contain the requirements for continuing to provide psychiatric services to these specialized populations.
- Other technical edits.

Nursing Home- Hospital Long Term Care Unit Beds: The revisions to the CON Review Standards for NH-HLTCU Beds and Addendum for Special Population Groups include the following and became effective on September 21, 2017:

- Updated the Department name throughout the document.
- Section 2(1)(b): The Average Daily Census (ADC) adjustment factor definition was updated to apply a factor of 0.90 for all planning areas to reflect the overall change in occupancy and lengths of stay. This change was intended to improve access by setting all planning areas to the same adjustment factor when determining the nursing home bed need.
- Section 6: The high occupancy provisions were revised to be facility specific, not county, based on the current environment of shorter lengths of stay and managed care.
- Section 9: Language was added that clarifies requirements for a new entity with no prior NH-HLTCU history that is applying to acquire a NH-HLTCU.
- Section 10: The criteria for a Bariatric patient room has been updated and clarified.
- Section 14: Language was added to clarify that nursing home replacement will not be subject to comparative review if the new site is within the same planning area as the existing site. Reduced regulation provides facilities more opportunities for submitting an application versus the current three times a year.
- Information contained in Appendix B will be moved to the Department website as opposed to being imbedded in the standard.
- Appendices C and E were removed as they are no longer needed due to other changes in the standards.
- In the statewide pool for the needs of special population groups addendum, the requirements to initiate hospice beds were removed as they are no longer needed, and requirements to initiate and acquire Bariatric patient beds were added along with corresponding project delivery requirements as there is an increased need for this special population group.
- The method for adjusting and redistributing the number of beds available in the statewide pool for the needs of special population groups was revised.
- Other technical edits.

During FY2018, the CON Commission revised the review standards for Surgical Services and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services.

Surgical Services: The revisions to the CON Review Standards for Surgical Services include the following and became effective on November 17, 2017:

- Updated the Department name throughout the document.
- Section 4(3)(a): Added language regarding commitment letters and the use of historical surgical cases for initiation.
- Section 11(2)(e): Added new language regarding commitment letters and the use of historical surgical cases for initiation as shown below. Less regulation will ease the process for the applicant when using its own data to initiate:

  - (e) SUBSECTION 11(2)(d) SHALL NOT APPLY IF THE PROPOSED PROJECT INVOLVES THE INITIATION OF A SURGICAL SERVICE AT A NEW FSOF OR A NEW ASC AT A NEW GEOGRAPHICAL SITE UTILIZING THE HISTORICAL SURGICAL CASES OF THE APPLICANT AND THE NEW SERVICE IS OWNED BY THE SAME APPLICANT. THE APPLICANT FACILITY COMMITTING SURGICAL DATA HAS COMPLETED THE DEPARTMENTAL FORM THAT CERTIFIES THE SURGICAL CASES WERE PERFORMED AT THE COMMITTING FACILITY AND THE SURGICAL CASES WILL BE TRANSFERRED TO THE PROPOSED SURGICAL FACILITY FOR NO LESS THAN 3 YEARS SUBSEQUENT TO THE INITIATION OF THE SURGICAL SERVICE PROPOSED BY THE APPLICANT.
- Other technical edits.

Urinary Extracorporeal Shock Wave Lithotripsy: The revisions to the CON Review Standards for UESWL Services include the following and became effective on March 29, 2018:

- Updated the Department name throughout the document.
- Section 3(1)(c)(iii) and (vii): Free-standing Surgical Outpatient Facilities (FSOF) and Ambulatory Surgical Centers (ASC) sites can't typically meet these requirements. The change is to modernize the CON standards.
  - EITHER on-site OR THROUGH A CONTRACTUAL AGREEMENT WITH ANOTHER HEALTH FACILITY, IV supplies and materials for infusions and medications, blood and blood products, and pharmaceuticals, including vasopressor medications, antibiotics, and fluids and solutions.
  - EITHER on-site OR THROUGH A CONTRACTUAL AGREEMENT WITH ANOTHER HEALTH FACILITY, A 23-hour holding unit.
- Section 3(2): Added requirements to convert from mobile to fixed UESWL services. The change is consistent with other CON covered mobile modalities that offer conversion and is meant to increase access and decrease costs.
  - (2) AN APPLICANT PROPOSING TO INITIATE A FIXED UESWL SERVICE THAT MEETS THE FOLLOWING REQUIREMENTS SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH SUBSECTION (1)(B):
  - (a) THE APPLICANT IS CURRENTLY AN EXISTING MOBILE UESWL HOST SITE.
  - (b) THE APPLICANT HOSPITAL HAS PERFORMED AN AVERAGE OF AT LEAST 500 PROCEDURES ANNUALLY FOR THE PAST THREE YEARS PRIOR TO SUBMITTING AN APPLICATION.
  - (c) THE APPLICANT HOSPITAL OPERATES AN EMERGENCY ROOM THAT PROVIDES 24-HOUR EMERGENCY CARE SERVICES AND AT LEAST 80,000 VISITS WITHIN THE MOST RECENT 12-MONTH PERIOD FOR WHICH DATA, VERIFIABLE BY THE DEPARTMENT, IS AVAILABLE.
  - (d) THE APPLICANT HOSPITAL SHALL INSTALL AND OPERATE THE FIXED UESWL UNIT AT THE SAME SITE AS THE EXISTING HOST SITE.
  - (e) THE APPLICANT HOSPITAL SHALL CEASE OPERATION AS A HOST SITE AND NOT BECOME A HOST SITE FOR AT LEAST 12 MONTHS FROM THE DATE THE FIXED SERVICE BECOMES OPERATIONAL.
- Section 4(2): Removed the volume requirement for replacement. This is similar to other CON covered clinical services.
- Section 4(3): Modified as follows. This will still allow for conversion from fixed to mobile, but the service will have to demonstrate compliance with the volume

requirement. If a host site was converted to a fixed unit for better access to UESWL services at that site, then converting it back to a mobile unit seems to defeat that purpose. This language was originally written to convert fixed units to mobile.
Section 4(3): An applicant PROPOSING TO REPLACE 1 existing fixed UESWL unit with 1 mobile UESWL unit SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING.:

- (a) EACH EXISTING UESWL UNIT OF THE SERVICE PROPOSING TO REPLACE A UESWL UNIT HAS AVERAGED AT LEAST 1,000 UESWL PROCEDURES PER UNIT DURING THE MOST RECENT CONTINUOUS 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

- Section 4(4): The 36-month in operation requirement is waived if one of the following has been met. Reduced regulation allows for facilities to more easily replace an existing fixed UESWL service to a new location in certain situations that are unforeseen to the applicant. This change is consistent with other CON Standards.
  - (i) THE OWNER OF THE BUILDING WHERE THE SITE IS LOCATED HAS INCURRED A FILING FOR BANKRUPTCY UNDER CHAPTER SEVEN (7) WITHIN THE LAST THREE YEARS;
  - (ii) THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL;

  Removed volume requirements for replacement of an existing fixed UESWL service and its unit(s) to a new site in certain situations that are unforeseen to the applicant This change is consistent with other CON Standards.
  - (i) THE OWNER OF THE BUILDING WHERE THE SITE IS LOCATED HAS INCURRED A FILING FOR BANKRUPTCY UNDER CHAPTER SEVEN (7) WITHIN THE LAST THREE YEARS;
  - (ii) THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL; OR
  - (iii) THE UESWL SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF AN ENTIRE HOSPITAL TO A NEW GEOGRAPHIC SITE AND HAS ONLY ONE (1) UESWL UNIT.
- Section 6 has been modified to allow for the acquisition of a fixed or mobile UESWL service not meeting volume requirements by an entity if the UESWL service is 1) owned by the applicant, 2) is under common control by the applicant, or 3) has a common parent as the applicant. The acquisition of an UESWL service does not change the location of the service. The service would have to meet all other applicable UESWL standards and project delivery requirements. Reduced regulation allows for facilities to more easily realign their assets when part of a larger health system.
- Section 7(4) has been removed. This will give mobile routes more flexibility to change the route to accommodate changes that may be caused by facilities converting to a fixed unit.
- Appendix A: The factor for calculating projected UESWL procedures has been updated.
- Other technical edits.

The following review standards were reviewed with an anticipated completion in FY2019:

Hospital Beds: Proposed action was taken by the Commission at its March 27, 2018 meeting. The standards were submitted to the joint legislative committee (JLC) and a Public Hearing was held. The Commission took final action at its June 14, 2018 Commission meeting and were

submitted to the JLC and Governor for the required 45-day review period. Standards will become effective in FY2019.

Cardiac Catheterization Services: Proposed action was taken by the Commission at its June 14, 2018 meeting. The standards were submitted to the joint legislative committee (JLC) and a Public Hearing was held. The Commission took final action at its September 20, 2018 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period. Standards will become effective in FY2019.

Open Heart Surgery Services: Proposed action was taken by the Commission at its June 14, 2018 meeting. The standards were submitted to the joint legislative committee (JLC) and a Public Hearing was held. The Commission took final action at its September 20, 2018 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period. Standards will become effective in FY2019.

FY2017 CON ANNUAL ACTIVITY REPORT – ATTACHMENT C

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) PROGRAM

ANNUAL ACTIVITY REPORT

October 2016 through September 2017
(FY2017)

Michigan Department of Health & Human Services
RICK SNYDER, GOVERNOR | NICK LYON, DIRECTOR

http://www.michigan.gov/con

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FY2017 CON ANNUAL ACTIVITY REPORT – ATTACHMENT C

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EXECUTIVE SUMMARY

One of the Michigan Department of Health and Human Services (MDHHS or Department) duties under Part 222 of the Public Health Code, MCL 333.22221(b), is to report to the Certificate of Need (CON) Commission annually on the Department's performance under this Part. This is the Department's 29th report to the Commission and covers the period beginning October 1, 2016, through September 30, 2017 (FY 2017). Data contained in this report may differ from prior reports due to updates subsequent to each report's publishing date.

Administration

The Department through its Policy, Planning and Legislative Services Administration provides support for the CON Commission (Commission) and its Standard Advisory Committees (SACs). The Commission is responsible for setting review standards and designating the list of covered services. The Commission may utilize a SAC to assist in the development of proposed CON review standards, which consists of a 2/3 majority of experts in the subject area. Further, the Commission, if determined necessary, may submit a request to the Department to engage the services of consultants or request the Department to contract with an organization for professional and technical assistance and advice or other services to assist the Commission in carrying out its duties and functions.

The Department, through its CON Evaluation Section, manages and reviews all incoming Letters of Intent, applications and amendments. These functions include determining if a CON is required for a proposed project as well as providing the necessary application materials, when applicable. In addition, the Section is responsible for monitoring implementation of approved projects, as well as the compliance with the terms and conditions of approvals.

During FY 2017, the Department has continued to make process improvements in both the Policy and Evaluation Sections. The revised CON administrative rules were promulgated and became effective in December 2016, which now allows for a change in site for an approved CON if certain requirements are met.

The Evaluation Section completed enhancements to the CON Annual Survey tool for proper submission and validation of nursing home patient days of care data which resulted in more accurate bed need calculation for this service. The Section successfully completed review and approval of applicants for special pool psychiatric beds under the newly established review standards. The Department completed a statewide compliance review of all facilities providing cardiac catheterization and MRT services. The Section also facilitated several webinars to provide up-to-date information on revised standards and project delivery requirements, and CON reporting requirements.

The Policy Section assisted the Commission to make the necessary modifications to the CON Review standards to better reflect practice, improve quality, reduce regulation to replace equipment, and to add clarity to the MRI services standards; added special population groups for developmentally disabled, geriatrics, and medical psychiatric to provide more access to psychiatric beds for these specific hard to place patients; removed dental CT scanners from CON regulation for dentists; and added clarifying language to NICU & Special Newborn Nursing Services.

These initiatives have greatly increased the availability of CON information and data to improve and streamline the review process, better inform policy makers and enhance community knowledge about Michigan's healthcare system.

CON Required

In accordance with MCL 333.22209, a person or entity is required to obtain a Certificate of Need, unless elsewhere specified in Part 222, for any of the following activities:

- Acquire an existing health facility or begin operation of a health facility
- Make a change in the bed capacity of a health facility
- Initiate, replace, or expand a covered clinical service
- Make a covered capital expenditure.

CON Application Process

To apply for a CON, the following steps must be completed:

- Letter of Intent filed and processed prior to submission of an application
- CON application filed on appropriate date as defined in the CON Administrative Rules
- Application reviewed by the Evaluation Section
- Issuance of Proposed Decision by the Policy and Legislative Administration
    - Appeal if applicant disagrees with the Proposed Decision issued
- Issuance of the Final Decision by the MDHHS Director.

There are three types of CON review: nonsubstantive, substantive individual, and comparative. The Administrative Rules for the CON program establish time lines by which the Department must issue a proposed decision on each CON application. The proposed decision for a nonsubstantive review must be issued within 45 days of the date the review cycle begins, 120 days for substantive individual, and 150 days for comparative reviews.

FY 2017 in Review

In FY 2017, there were 341 Letters of Intent received resulting in 275 applications filed for CON review and approval. In addition, the Department received 67 amendments to previously approved applications. In total, the Department approved 266 proposed projects resulting in approximately $1,376,478,567 of new capital expenditures into Michigan's healthcare system. The Department also surveyed 1,098 facilities and collected statistical data.

As required by Administrative Rules, the Department was timely in processing Letters of Intent, pending CON applications and issuing its decisions on pending applications. These measures, along with the other information contained in this report, aid the Commission in its duties as set forth in Part 222 of the Public Health Code.

During FY2017, the CON Commission revised the review standards for Computed Tomography (CT) Services, Magnetic Resonance Imaging (MRI) Services, Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services, Nursing Home and Hospital Long-Term Care Unit (NH-HLTCU) Beds and Addendum for Special Population Groups, and Psychiatric Beds and Services.

This report is filed by the Department in accordance with MCL 333.22221(f). The report presents information about the nature of these CON applications and decisions, as well as the Commission's actions during the reporting period. Several tables include benchmarks for timely processing of applications and issuing decisions as set forth in the CON Administrative Rules. Note that the data in the report represents some applications that were carried over from last fiscal year while others may be carried over into next fiscal year.

HISTORICAL OVERVIEW OF MICHIGAN'S CERTIFICATE OF NEED PROGRAM

1972 Legislation was introduced in the Michigan legislature to enact the Certificate of Need (CON) program. The Michigan CON program became effective on April 1, 1973.

1974 Congress passed the National Health Planning and Resources Development Act (PL 93-641) including funding incentives that encouraged states to establish a CON program. The purpose of the act was to facilitate recommendations for a national health planning policy. It encouraged state planning for health services, manpower, and facilities. And, it authorized financial assistance for the development of resources to implement that policy. Congress repealed PL 93-641 and certificate of need in 1986. At that time, federal funding of the program ceased and states became totally responsible for the cost of maintaining CON.

1988 Michigan's CON Reform Act of 1988 was passed to develop a clear, systematic standards development process and reduce the number of services requiring a CON.

Prior to the 1988 CON Reform Act, the Department found that the program was not serving the needs of the state optimally. It became clear that many found the process to be excessively unclear and unpredictable. To strengthen CON, the 1988 Act established a specific process for developing and approving standards used in making CON decisions. The review standards establish how the need for a proposed project must be demonstrated. Applicants know before filing an application what specific requirements must be met.

The Act also created the CON Commission. The CON Commission, whose membership is appointed by the Governor, is responsible for approving CON review standards. The Commission also has the authority to revise the list of covered clinical services subject to CON review. However, the CON sections inside the Department are responsible for day-to-day operations of the program, including supporting the Commission and making decisions on CON applications consistent with the review standards.

1993 Amendments to the 1988 Act required ad hoc committees to be appointed by the Commission to provide expert assistance in the formation of the review standards.

2002 Amendments to the 1988 Act expanded the CON Commission to 11 members, eliminated the previous ad hoc committees, and established the use of Standard Advisory Committees or other private consultants/organizations for professional and technical assistance.

Present The CON standards now allow applicants to reasonably assess requirements for approval, before filing an application. As a result, there are far fewer appeals of Department decisions. Moreover, the 1988 amendments appear to have reduced the number of unnecessary applications, i.e., those involving projects for which a need cannot be demonstrated.

The standards development process now provides a public forum and involves organizations representing purchasers, payers, providers, consumers, and experts in the subject matter. The process has resulted in CON review standards that are legally enforceable, while assuring that standards can be revised promptly in response to the changing healthcare environment.

ADMINISTRATION OF THE CERTIFICATE OF NEED PROGRAM

Commission The Commission is an 11-member body. The Commission, appointed by the Governor and confirmed by the Senate, is responsible for approving CON review standards used by the Department to make decisions on individual CON applications. The Commission also has the authority to revise the list of covered clinical services subject to CON review. Appendix I is a list of the CON Commissioners for FY2015.

NEWTAC The New Technology Advisory Committee is a standing committee responsible for advising the Commission on the new technologies, including medical equipment and services that have not yet been approved by the federal Food and Drug Administration for commercial use.

SAC A Standards Advisory Committee (SAC) may be appointed by and report to the CON Commission. The SACs advise the Commission regarding creation of, or revisions to the standards. The Committees are composed of a 2/3 majority of experts in the subject matter and include representatives of organizations of healthcare providers, professionals, purchasers, consumers, and payers.

MDHHS The Michigan Department of Health and Human Services is responsible for administering the CON program and providing staffing support for the Commission. This includes promulgating applicable rules, processing and rendering decisions on applications, and monitoring and enforcing the terms and conditions of approval. These functions are within the Policy and Legislative Administration.

Policy Section The Policy Section within the Administration provides professional and support staff assistance to the Commission and its committees in the development of new and revised standards. Staff support includes researching issues related to specific standards, preparing draft standards, and performing functions related to both Commission and Committee meetings.

Evaluation Section The Evaluation Section, also within the Administration, has operational responsibility for the program, including providing assistance to applicants prior to and throughout the CON process. The Section is responsible for reviewing all Letters of Intent and applications as prescribed by the Administrative Rules. Staff determines if a proposed project requires a CON. If a CON is required, staff identifies the appropriate application forms for completion by the applicant and submission to the Department. The application review process includes the assessment of each application for compliance with all applicable statutory requirements and CON review standards, and preparation of a Program Report and Finance Report documenting the analysis and findings. These findings are used by the Director to make a final decision to approve or deny a project.

In addition to the application reviews, the Section reviews requests for amendments to approved CONs as allowed by the Rules. Amendment requests involve a variety of circumstances, including changes in how an approved project is financed and authorization for cost overruns. The Section is also responsible for monitoring the implementation of approved projects, as well as the long-term compliance with the terms and conditions of approvals.

The Section also provides the Michigan Finance Authority (MFA) with information when healthcare entities request financing through MFA bond issues and Hospital Equipment Loan Program (HELP) loans. This involves advising on whether a CON is required for the item(s) that will be bond financed.

CERTIFICATE OF NEED PROCESS

The following discussion briefly describes the steps an applicant follows in order to apply for a Certificate of Need.

Letter of Intent — An applicant must file an LOI with the Department and, if applicable, the regional CON review agency. The CON Evaluation Section identifies for an applicant all the necessary application forms required based on the information contained in the LOI.

Application — On or before the designated application date, an applicant files an application with the Department and the regional review agency, if applicable. The Evaluation Section reviews an application to determine if it is complete. If not complete, additional information is requested. The review cycle starts after an application is deemed complete or received in accordance with the Administrative Rules.

Review Types and Time Frames — There are three review types: nonsubstantive, substantive individual and comparative. Nonsubstantive reviews involve projects such as replacement of covered equipment or changes in ownership that do not require a full review. Substantive individual reviews involve projects that require a full review but are not subject to comparative review as specified in the applicable CON review standards. Comparative reviews involve situations where two or more applicants are competing for a resource limited by a CON review standard, such as hospital and nursing home beds. The maximum review time frames for each review type, from the date an application is deemed complete or received until a proposed decision is issued, are: 45 days for nonsubstantive, 120 for substantive individual and 150 days for comparative reviews. The comparative review time frame includes an additional 30-day period for determining if a comparative review is necessary. Whenever this determination is made, the review cycle begins for comparative reviews.

Review Process — The Evaluation Section reviews the application. Each application is reviewed separately unless part of a comparative review. Each application review includes a program and finance report documenting the Department's analysis and findings of compliance with the statutory review criteria, as set forth in Section 22225 of the Public Health Code and the applicable CON review standards.

Proposed Decision — The Policy and Legislative Administration in which the Evaluation Section resides issues a proposed decision to the applicant within the required time frame. This decision is binding unless reversed by the Department Director or appealed by the applicant. The applicant must file an appeal within 15 days of receipt of the proposed decision if the applicant disagrees with the proposed decision or its terms and conditions. In the case of a comparative review, a single decision is issued for all applications in the same comparative group.

Final Decision — If the proposed decision is not appealed, a final decision is made by the Director of the Department in accordance with MCL 333.22231. If a hearing on the proposed decision is requested, the final decision by the Director is not issued until completion of the hearing and any filing of exceptions to the proposed decision by the Michigan Administrative Hearing System. A final decision by the Director may be appealed to the applicable circuit court.

LETTERS OF INTENT

The CON Administrative Rules, specifically Rule 9201, provides that Letters of Intent (LOI) must be processed within 15 days of receipt. Processing an LOI includes entering data in the management information system, verifying historical facility information, and obtaining proof of authorization to do business in Michigan. This information determines the type of review for the proposed project, and the Department then notifies the applicant of applicable application forms to be completed.

Table 1 provides an overview of the number of LOIs received and processed in accordance with the above-referenced Rule.

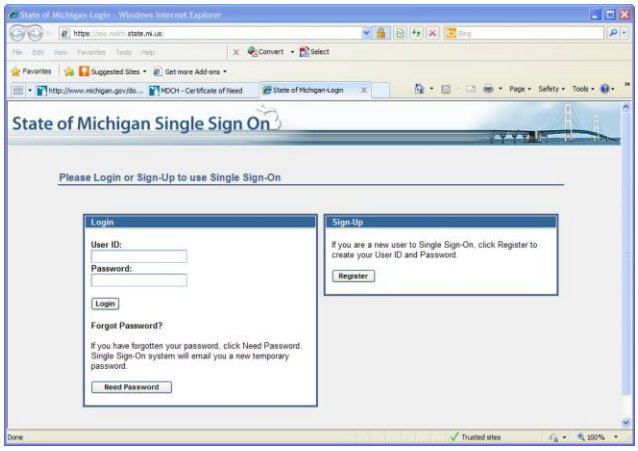
TABLE 1
LETTERS OF INTENT RECEIVED AND PROCESSED WITHIN 15 DAYS
FY2013 - FY2017

	LOIs Received	Processed within 15 Days	Percent Processed within 15 Days	Waivers Processed*
FY2013	440	438	99%	61
FY2014	333	332	99%	39
FY2015	435	434	99%	44
FY2016	442	439	99%	71
FY2017	341	340	99%	24

* Waivers are proposed projects that do not require CON review, but an LOI was submitted for Department's guidance/confirmation.

In FY 2017, LOIs were processed in a timely manner as required by Administrative Rule and available for public viewing on the online application system. The online system allows for faster processing of LOIs and subsequent applications by the Evaluation Section, as well as modifying these applications by applicants when needed.

In 2006, Michigan became the first state to have an online application and information system. Today 100% of all LOIs and applicable applications are submitted online.



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TYPES OF CERTIFICATE OF NEED APPLICATION REVIEWS

The Administrative Rules also establish three types of project reviews: nonsubstantive, substantive individual, and comparative. The Rules specify the time frames by which the Bureau (Evaluation Section) must issue its proposed decision related to a CON application. The time allowed varies based on the type of review.

Nonsubstantive

Nonsubstantive reviews involve projects that are subject to CON review but do not warrant a full review. The following describes types of projects that are potentially eligible for nonsubstantive review:

- Acquire an existing health facility
- Replace a health facility within the replacement zone and below the covered capital expenditure

- Add a host site to an existing mobile network/route that does not require data commitments
- Replace or upgrade a covered clinical equipment
- Acquire or relocate an existing freestanding covered clinical service.

The Rules allow the Bureau (Evaluation Section) up to 45 days from the date an application is deemed complete to issue a proposed decision. Reviewing these types of proposed projects on a nonsubstantive basis allows an applicant to receive a decision in a timely fashion while still being required to meet current CON requirements, including quality assurance standards.

Substantive Individual

Substantive individual review projects require a full review but are not subject to comparative review and not eligible for nonsubstantive review. An example of a project reviewed on a substantive individual basis is the initiation of a covered clinical service such as Computed Tomography (CT) scanner services. The Bureau (Evaluation Section) must issue its proposed decision within 120 days of the date a substantive individual application is deemed complete or received.

Comparative

Comparative reviews involve situations where two or more applications are competing for a limited resource such as hospital or nursing home beds. A proposed decision for a comparative review project must be issued by the Bureau (Evaluation Section) no later than 120 days after the review cycle begins. The cycle begins when the determination is made that the project requires comparative review. According to the Rules, the Department has the additional 30 days to determine if, in aggregate, all of the applications submitted on a window date exceed the current need. A comparative window date is one of the three dates during the year on which projects subject to comparative review must be filed. Those dates are the first working day of February, June, and October.

Section 22229 established the covered services and beds that were subject to comparative review. Pursuant to Part 222, the CON Commission may change the list subject to comparative review.

Figure 1 delineates services/beds subject to comparative review.

FIGURE 1 *Services/Beds Subject to Comparative Review in FY2017*	
Neonatal Intensive Care Unit	Nursing Home/HLTCU Beds
Hospital Beds	Nursing Home Beds for Special Population Groups
Psychiatric Beds	Psychiatric Beds for Special Population Groups
Transplantations	

Note: See individual CON review standards for more information.

Table 2 shows the number of applications received by the Department by review type.

TABLE 2 *APPLICATIONS RECEIVED BY REVIEW TYPE* *FY2013 - FY2017*					
	FY2013	**FY2014**	**FY2015**	**FY2016**	**FY2017**
Nonsubstantive*	161	117	194	171	186
Substantive Individual	152	114	129	148	89
Comparative	8	2	0	0	0
TOTALS	321	233	323	319	275

* Includes 1 swing bed application.

Table 3 provides a summary of applications received and processed in accordance with Rule 9201. The Rule requires the Evaluation Section to determine if additional information is needed within 15 days of receipt of an application. Processing of applications includes: updating the management information system, verifying submission of required forms, and determining if other information is needed in response to applicable Statutes and Standards.

TABLE 3
APPLICATIONS RECEIVED AND PROCESSED WITHIN 15 DAYS
FY2013 - FY2017

	FY2013	FY2014	FY2015	FY2016	FY2017
Applications Received	326	235	326	320	275
Processed within 15 Days	326	235	324	318	272
Percent Processed within 15 Days	100%	100%	99%	99%	99%

Note: Includes swing bed applications.

Table 4 provides an overview of the average number of days taken by the Evaluation Section to complete reviews by type.

TABLE 4
AVERAGE NUMBER OF DAYS IN REVIEW CYCLE BY REVIEW TYPE
FY2013- FY2017

	FY2013	FY2014	FY2015	FY2016	FY2017
Nonsubstantive	38	40	42	38	41
Substantive Individual	117	117	112	104	116
Comparative	119	116	N/A	N/A	N/A

Note: Average review cycle accounts for extensions requested by applicants.

EMERGENCY CERTIFICATES OF NEED

Table 5 shows the number of emergency CONs issued. The Department is authorized by Section 22235 of the Public Health Code to issue emergency CONs when applicable. Rule 9227 permits up to 10 working days to determine if an emergency application is eligible for review under Section 22235. Although it is not required by Statute, the Bureau (Evaluation Section) attempts to issue emergency CON decisions to the Director for final review and approval within 10 days from receipt of request.

TABLE 5
EMERGENCY CON DECISIONS ISSUED
FY2013 - FY2017

	FY2013	FY2014	FY2015	FY2016	FY2017
Emergency CONs Issued	5	2	2*	0*	0
Percent Issued within 10 Working Days	100%	100%	100%	N/A	N/A

*Emergency CON application was submitted but withdrawn before a decision was to be issued.

PROPOSED DECISIONS

Part 222 establishes a 2-step decision making process for CON applications that includes both a proposed decision and final decision. After an application is deemed complete and reviewed by the Evaluation Section, a proposed decision is issued by the Bureau (Evaluation Section) to the applicant and the Department Director according to the timeframes established in the Rules.

Table 6 shows the number of proposed decisions by type, issued within the applicable timeframes set forth in the Administrative Rules 325.9206 and 325.9207: 45 days for nonsubstantive, 120 days for substantive individual, and 150 days for comparative reviews, or any requested extension(s) to the review cycle.

TABLE 6
PROPOSED DECISIONS ISSUED
FY2013- FY2017

	Nonsubstantive		Substantive Individual		Comparative	
	Issued	Issued on Time	Issued	Issued on Time	Issued	Issued on Time
FY2013	147	100%	145	100%	9	100%
FY2014	119	100%	130	100%	6	100%
FY2015	195	100%	118	100%	0	N/A
FY2016	169	100%	138	100%	0	N/A
FY2017	167	100%	99	100%	0	N/A

Table 7 compares the number of proposed decisions by decision type made.

TABLE 7
COMPARISON OF PROPOSED DECISIONS BY DECISION TYPE
FY2013- FY2017

	Approved	Approved w/ Conditions	Disapproved	Percent Disapproved	TOTAL
FY2013	261	35	10	3%	306
FY2014	222	28	7	3%	257
FY2015	261	53	1	0.3%	315
FY2016	226	81	0	0%	307
FY2017	205	61	0	0%	266

Note: Not all proposed decisions issued in a given year will have a final decision in the same year.

If a proposed decision is disapproved, an applicant may request an administrative hearing that suspends the time frame for issuing a final decision. After a proposed disapproval is issued, an applicant may also request that the Department consider new information. The Administrative Rules allow an applicant to submit new information in response to the areas of noncompliance identified by the Department's analysis of an application and the applicable Statutory requirements to satisfy the requirements for approval.

FINAL DECISIONS

The Director issues a final decision on a CON application following either a proposed decision or the completion of a hearing, if requested, on a proposed decision. Pursuant to Section 22231(1) of the Public Health Code, the Director may issue a decision to approve an application, disapprove an application, or approve an application with conditions or stipulations. If an application is approved with conditions, the conditions must be explicit and relate to the proposed project. In addition, the conditions must specify a time period within which the conditions shall be met, and that time period cannot exceed one year after the date the decision is rendered. If approved with stipulations, the requirements must be germane to the proposed project and agreed to by the applicant.

This section of the report provides a series of tables summarizing final decisions for each of the review thresholds for which a CON is required. It should be noted that some tables will not equal other tables, as many applications fall into more than one category.

Table 8 and **Figure 2** display the number of final decisions issued.

TABLE 8 *FINAL DECISIONS ISSUED FY2013- FY2017*	
FY2013	309
FY2014	256
FY2015	316
FY2016	303
FY2017	272

FIGURE 2
FY 2017 FINAL DECISIONS ISSUED BY HEALTH SERVICE AREAS

Note: Figure 2 does not include 7 out-state decisions.

Table 9 summarizes final decisions by review categories defined in MCL 333.22209(1) and as summarized below:

Acquire, Begin Operation of, or Replace a Health Facility
Under Part 222, a health facility is defined as a general hospital, hospital long-term care unit, psychiatric hospital or unit, nursing home, freestanding surgical outpatient facility (FSOF), and health maintenance organization under limited circumstances. This category includes projects to construct or replace a health facility, as well as projects involving the acquisition of an existing health facility through purchase or lease.

Change in Bed Capacity
This category includes projects to increase in the number of licensed hospital, nursing home, or psychiatric beds; change the licensed use; and relocate existing licensed beds from one geographic location to another without an increase in the total number of beds.

Covered Clinical Services
This category includes projects to initiate, replace, or expand a covered clinical service: neonatal intensive care services, open heart surgery, extrarenal organ transplantation, extracorporeal shock wave lithotripsy, megavoltage radiation therapy, positron emission tomography, surgical services, cardiac catheterization, magnetic resonance imaging services, computed tomography scanner services, and air ambulance services.

Covered Capital Expenditures
This category includes capital expenditure project in a clinical area of a licensed health facility that is equal to or above the threshold set forth in Part 222. Typical examples of covered capital expenditure projects include construction, renovation, or the addition of space to accommodate increases in patient treatment or care areas not already covered. In 2016 the covered capital expenditure threshold was $3,180,000 and as of January 1, 2017, the covered capital expenditure threshold was increased to $3,187,500. The threshold is updated in January of every year.

TABLE 9 *FINAL DECISIONS ACTIVITY CATEGORY FY2013 - FY2017*					
Approved	**FY2013**	**FY2014**	**FY2015**	**FY2016**	**FY2017**
Acquire, Begin, or Replace a Health Facility	38	47	68	26	47
Change in Bed Capacity	52	46	34	42	26
Covered Clinical Services	241	191	214	240	167
Covered Capital Expenditures	44	47	33	49	65
Disapproved					
Acquire, Begin, or Replace a Health Facility	2	4	0	0	0
Change in Bed Capacity	5	5	1	0	0
Covered Clinical Services	0	0	1	0	0
Covered Capital Expenditures	3	5	1	0	0

Note: Totals above may not match Final Decision totals because one application may include multiple categories.

Table 10 provides a comparison of the total number of final decisions and total project costs by decision type.

TABLE 10 *COMPARISON OF FINAL DECISIONS BY DECISION TYPE FY2013 - FY2017*				
	Approved	**Approved With Conditions**	**Disapproved**	**Totals**
Number of Final Decisions				
FY2013	268	36	5	309
FY2014	223	28	5	256
FY2015	261	53	2	316
FY2016	224	79	0	303
FY2017	208	64	0	272
Total Project Costs				
FY2013	$ 724,546,360	$ 239,908,373	$ 321,167,591	$ 1,285,622,324
FY2014	$ 904,329,614	$ 196,996,469	$ 39,529,999	$ 1,140,856,082
FY2015	$ 2,077,265,073	$ 239,911,843	$ 5,554,114	$ 2,322,741,030
FY2016	$ 1,000,284,403	$ 314,369,908	$ 0	$ 1,314,654,311
FY2017	$ 1,069,086,777	$ 307.391,790	$ 0	$ 1,376,478,567

Note: Final decisions include emergency CON applications.

In FY2017, there were no CON applications that received a final decision of disapproval from the Department.

CERTIFICATE OF NEED ACTIVITY SUMMARY COMPARISON

Table 11 provides a comparison for various stages of the CON process.

TABLE 11
CON ACTIVITY COMPARISON
FY2013 - FY2017

	Number of Applications	Difference from Previous Year	Total Project Costs	Difference from Previous Year
Letters of Intent Processed				
FY2013	440	4%	$1,661,621,556	(16%)
FY2014	333	(24%)	$1,282,834,192	(23%)
FY2015	435	31%	$2,894,486,078	126%
FY2016	442	2%	$1,527,863,597	(47%)
FY2017	341	(23%)	$1,864,251,305	22%
Applications Submitted				
FY2013	326	6%	$1,539,877,626	14%
FY2014	235	(28%)	$ 904,601,983	(41%)
FY2015	326	39%	$2,526,962,926	179%
FY2016	320	(2%)	$1,235,892,460	(51%)
FY2017	275	(14%)	$1,598,240,431	29%
Final Decisions Issued				
FY2013	309	9%	$1,285,622,324	7%
FY2014	256	(17%)	$1,140,856,082	(11%)
FY2015	316	23%	$2,322,741,030	104%
FY2016	303	(4%)	$1,314,654,311	(43%)
FY2017	272	(10%)	$1,376,478,567	5%

Note: Applications submitted and final decisions Issued include Emergency CONs and swing bed applications.

AMENDMENTS

The Rules allow an applicant to request to amend an approved CON for projects that are not complete. The Department has the authority to decide when an amendment is appropriate or when the proposed change is significant enough to require a separate application. Typical reasons for requesting amendments include:

- **Cost overruns -** The Rules allow the actual cost of a project to exceed the approved amount by 15 percent of the first $1 million and 10 percent of all costs over $1 million. Fluctuations in construction costs can cause projects to exceed approved amounts
- **Changes in the scope of a project -** An example is the addition of construction or renovation required by regulatory agencies to correct existing code violations that an applicant did not anticipate in planning the project or a change in covered clinical equipment.
- **Changes in financing -** Applicants may decide to pursue a financing alternative better than the financing that was approved in the CON.
- **Change in construction start date** – The Rules allow an Applicant to request an extension to start construction/renovation for an approved project.

Table 12 provides a summary of amendment requests received by the Department and the time required to process and issue a decision. Rule 9413 permits that the review period for a request to amend a CON-approved project be no longer than the original review period.

TABLE 12
AMENDMENTS RECEIVED AND DECISIONS ISSUED
FY2013 - FY2017

	FY2013	FY2014	FY2015	FY2016	FY2017
Amendments Received	73	63	84	76	67
Amendment Decisions Issued	84	60	88	76	68
Percent Issued within Required Time Frame	100%	99%	100%	97%	100%

NEW CERTIFICATE OF NEED CAPACITY

Table 13 provides a comparison of existing covered services, equipment and facilities already operational to new capacity approved in FY 2017. Eighty one (81) of the 272 CON approvals in FY 2017 were for new or additional capacity. The remaining approvals were for replacement equipment, relocation of existing services, acquisitions, renovations and other capital expenditures.

TABLE 13
COVERED CLINICAL SERVICES AND BEDS
FY2017

Covered Clinical Services/Beds	Existing Sites	Existing Units/Beds	New Sites	New Units/Beds
Air Ambulances	13	16	1	1
Cardiac Catheterization Services	60	223	0	6
Primary PCI	1	N/A	0	N/A
Elective PCI	10	N/A	4	N/A
Open Heart Surgical Services	34	N/A	0	N/A
Surgical Services	252	1,380	2	12
CT Scanners Services	244	378	12	10
MRI Services	265	306	10	4
PET Services	94	24	2	3
Lithotripsy Services	83	10	2	0
MRT Services	68	120	1	1
Transplant Services	6	N/A	0	N/A
Hospitals	181	26,047	2	0
NICU Services	21	634	0	6
SCN Services	15	91	0	0
Extended Care Services Program (Swing Beds)	31	288	1	5
Nursing Homes/HLTCU	468	48,373	3	160
Psychiatric Hospitals/Units	60	2,418	7	279
Psychiatric Flex Beds	3	38	1	8

Note: The source for the existing site and unit/bed information for Table 13 was the 2016 CON Annual Survey, and CON applications approved but not yet operational. Table 13 does not account for projects expired facilities closed and beds delicensed and returned to the various bed pools since the last survey period for CY 2016. New sites include mobile host sites for CT, Lithotripsy, MRI and PET services.

COMPLIANCE ACTIONS

Table 14 shows there were 303 projects requiring follow-up for FY 2017 based on the Department's Monthly Follow-up/Monitoring Report as shown below.

TABLE 14
FOLLOW UP AND COMPLIANCE ACTIONS
FY2013 - FY2017

	FY2013	FY2014	FY2015	FY2016	FY2017
Projects Requiring 1-yr Follow-up	340	350	251	314	303
Approved CONs Expired	127	97	95	51	78
Compliance Orders Issued	1	6	30	10	54

Note: CONs are expired due to non-compliance with terms and conditions of approval or when the recipient has notified the Department that either the approved-project was not implemented or the site is no longer providing the covered service/beds. Compliance Orders include orders issued by the Department under MCL 333.22247, settlement agreements offered or remedies for non-compliance. The Department completed a statewide compliance review of cardiac catheterization and MRT services. Other compliance orders issued included CT and cardiac catheterization services.

ANALYSIS OF CERTIFICATE OF NEED PROGRAM FEES AND COSTS

Section 20161(3) sets forth the fees to be collected for CON applications. **Figure 3A** shows the application fees that are based on total project costs effective until October 14, 2013.

FIGURE 3A
PREVIOUS CON APPLICATION FEES

Total Project Costs	CON Application Fee
$0 to $500,000	$1,500
$500,001 to $4,000,000	$5,500
$4,000,001 and above	$8,500

Figure 3B shows the application fees based on total projects costs and additional fees per the new fee structure, effective October 15, 2013, approved under House Bill No. 4787.

FIGURE 3B
CURRENT CON APPLICATION FEES

Total Project Costs	CON Application Fee
$0 to $500,000	$3,000
$500,001 to $3,999,999	$8,000
$4,000,000 to $9,999,999	$11,000
$10,000,000 and above	$15,000
Additional Fee Category	**Additional Fee**
Complex Projects (i.e. Comparative Review, Acquisition or replacement of a licensed health facility with two or more covered clinical services.)	$3,000
Expedited Review - Applicant Request	$1,000
Letter of Intent (LOI) Resulting in a Waiver	$500
Amendment Request to Approved CON	$500
CON Annual Survey	$100 per Covered Clinical Service

Table 15A, 15B analyzes the number of applications by fee assessed.

TABLE 15A
NUMBER OF CON APPLICATIONS BY FEE
FY2013 - FY2014

CON Fee	FY2013	FY2014A
$ 0*	6	0
$1,500	139	5
$5,500	97	8
$8,500	84	7
TOTAL	326	20

TABLE 15B
NUMBER OF CON APPLICATIONS BY FEE
FY2014 – FY2017

CON Fee	FY2014B	FY 2015	FY2016	FY2017
$ 0*	3	6	1	1
$3,000	103	146	166	95
$8,000	70	91	96	93
$11,000	23	36	27	42
$15,000	16	47	30	44
TOTAL	215	326	320	275

Note: Table 15A and 15B may not match fee totals in Table 16, as Table 16 accounts for refunds, overpayments, MFA funding, etc.

** No fees are required for emergency CON and swing beds applications.*

Table 15C analyzes the fees collected for the additional fee categories. More than one fee category may be assessed for one application.

TABLE 15C
NUMBER OF ADDITIONAL CON APPLICATIONS FEES
FY2014 – FY2017

CON Fee Category	FY2014B	FY 2015	FY2016	FY2017
Complex Project	8	3	0	9
Expedited Review	27	38	42	31
LOI Waiver*	37	34	69	23
Amendment*	32	44	54	56
Annual Survey (Facilities)	1,191	1,107	1,099	1,056

*Note: Some waivers and amendments do not require a fee based on the type of change requested.

Table 16 provides information on CON program costs and source of funds.

TABLE 16
CON PROGRAM
COST AND REVENUE SOURCES FOR FY2013– FY2017

	FY2013	FY2014	FY2015	FY2016	FY2017
Program Cost	$1,785,688	$1,967,395	$2,115,182	$2,051,035	$1,972,166
Fees/Funding	$1,508,118	$1,823,772	$2,620,083	$2,350,168	$2,293,095
Fees % of Costs	84%	93%	100%+	100%+	100%+

Source: MDHHS Budget and Finance Administration.

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY2017, the CON Commission revised the review standards for Computed Tomography (CT) Services, Magnetic Resonance Imaging (MRI) Services, Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services, Nursing Home and Hospital Long-Term Care Unit (NH-HLTCU) Beds and Addendum for Special Population Groups, and Psychiatric Beds and Services.

The revisions to the CON Review Standards for CT Services received final approval by the CON Commission on September 21, 2016 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective December 9, 2016. The final language changes include the following:

- Section 2: Definitions removed and/or updated, and the following definition has been modified as shown:
  - "CT scanner" means x-ray CT scanning systems capable of performing CT scans of the head, other body parts, or full body patient procedures including Positron Emission Tomography (PET)/CT scanner hybrids if used for CT only procedures. The term does not include emission computed tomographic systems utilizing internally administered single photon gamma ray emitters, positron annihilation CT systems, magnetic resonance, ultrasound computed tomographic systems, CT simulators used solely for treatment planning purposes in conjunction with an MRT unit, and non-diagnostic, intra-operative guidance tomographic units, AND DENTAL CT SCANNERS THAT generate a peak power of 5 kilowatts or less as certified by the manufacturer AND ARE specifically designed to generate CT images to facilitate dental procedures BY A LICENSED DENTIST UNDER THE PRACTICE OF DENTISTRY. Definitions removed and updated to de-regulate dental CT scanners used by dentists in the practice of dentistry. This will provide better access to the consumer and more flexibility to the provider in their practice.
- Section 3: Removed reference to dental CT as it's no longer.
- Old Section 4: Removed as it's no longer needed.
- New Section 4: Removed reference to dental CT as it's no longer needed.
- Old Section 6: Removed as it's no longer needed.
- New Section 5: Removed reference to dental CT as it's no longer needed.
- New Section 5(2): The 36-month in operation requirement is waived if one of the following has been met. Reduced regulation allows for facilities to more easily replace an existing fixed CT scanner service to a new location in certain situations that are unforeseen to the applicant (same as MRI language).
  - (ii) THE OWNER OF THE BUILDING WHERE THE SITE IS LOCATED HAS INCURRED A FILING FOR BANKRUPTCY UNDER CHAPTER SEVEN (7) WITHIN THE LAST THREE YEARS;
  - (iii) THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL;

  Removed volume requirements for replacement of an existing fixed CT service and its unit(s) to a new site in certain situations that are unforeseen to the applicant (same as MRI language):

  - (ii) THE OWNER OF THE BUILDING WHERE THE SITE IS LOCATED HAS INCURRED A FILING FOR BANKRUPTCY UNDER CHAPTER SEVEN (7) WITHIN THE LAST THREE YEARS;

  - (iii) THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL; OR
  - (iv) THE CT SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF AN ENTIRE HOSPITAL TO A NEW GEOGRAPHIC SITE AND HAS ONLY ONE (1) CT UNIT.
- Old Section 8: Removed as it's no longer needed if dental CT scanners are de-regulated.
- New Section 6: Modified to allow for the acquisition of a fixed or mobile CT scanner service not meeting volume requirements by an entity if the CT scanner service is 1) owned by the applicant, 2) is under common control by the applicant, or 3) has a common parent as the applicant. The acquisition of a CT scanner service does not change the location of the service. The service would have to meet all other applicable CT standards and project delivery requirements. Reduced regulation allows for facilities to more easily realign their assets when part of a larger health system (same as MRI language).
- Old Section 10: Removed as it's no longer needed.
- Old Section 12: Removed as it's no longer needed.
- Old Section 17: Removed as it's no longer needed.
- New Section 14(2)(c): Modified - Through the CON Annual Survey, freestanding facilities are stating that they can't meet this because they are not open 24 hours. This is a requirement that goes back to the 1980's and the Planning Policies. At the time, only hospitals were eligible to provide CT services. Freestanding facilities were added in 1990, and this requirement was maintained. Striking "on a 24-hour basis," still ensures that there is a physician available to make the final interpretation and makes it easier for all facilities to comply with making it more of a technical edit for clarity.
- New Section 14(2)(f): Through the CON Annual Survey, freestanding facilities are stating that they can't meet this because they are not open 24 hours. Again, this is a requirement that goes back to the 1980's and the Planning Policies. At the time, only hospitals were eligible to provide CT services. Freestanding facilities were added in 1990, and this requirement was maintained. This is a technical clarification ensuring that the appropriate facilities are complying with the requirement.
- Old Section 20(5) & (6): Removed as it's no longer needed.
- New Section 16: Removed reference to dental CT as it's no longer needed.
- Old Section 23(2): Removed as it's no longer needed.
- New Section 17(2): Removed reference to dental CT as it's no longer needed.
- Other technical edits.

The revisions to the CON Review Standards for MRI Services received final approval by the CON Commission on June 15, 2016 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective October 21, 2016. The final language changes include the following:

- Section 6 has been modified to allow for the acquisition of a fixed or mobile MRI service not meeting volume requirements by an entity if the MRI service is 1) owned by the applicant, 2) is under common control by the applicant, or 3) has a common parent as the applicant. The acquisition of an MRI service does not change the location of the service. The service would have to meet all other applicable MRI standards and project delivery requirements. Reduced regulation allows for facilities to more easily realign their assets when part of a larger health system.
- Other technical edits.

The revisions to the CON Review Standards for NICU and Special Newborn Nursing Services received final approval by the CON Commission on September 21, 2016 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective December 9, 2016. The final language changes include the following:

- Section 2(1)(v): Definition for "special care nursery services" or "SCN services" has been modified for clarity and what types of services are provided in SCNs. This is a technical edit that does not make any programmatic changes in CON regulation.
- Section 2(1)(w): Added a definition for "well newborn nursery services" and clarifying that well newborn nurseries do not require a CON. This is a technical edit that does not make any programmatic changes in CON regulation.
    - (w) "WELL NEWBORN NURSERY SERVICES" MEANS PROVIDING THE FOLLOWING SERVICES AND DOES NOT REQUIRE A CERTIFICATE OF NEED:

      (i) THE CAPABILITY TO PERFORM NEONATAL RESUSCITATION AT EVERY DELIVERY;

      (ii) EVALUATE AND PROVIDE POSTNATAL CARE FOR STABLE TERM NEWBORN INFANTS;

      (iii) STABILIZE AND PROVIDE CARE FOR INFANTS BORN AT 35 TO 37 WEEKS' GESTATION WHO REMAIN PHYSIOLOGICALLY STABLE; AND

      (iv) STABILIZE NEWBORN INFANTS WHO ARE ILL AND THOSE BORN LESS THAN 35 WEEKS OF GESTATION UNTIL THEY CAN BE TRANSFERRED TO A HIGHER LEVEL OF CARE FACILITY.
- Section 7(2)(c): Eliminated the language that limits the expansion of beds to no more than five. The current standard limits the expansion to no more than 5 beds even if the methodology calculation is higher. There is no need for this cap.
- Other technical edits.

The revisions to the CON Review Standards for Psychiatric Beds and Services received final approval by the CON Commission on September 21, 2016 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective December 9, 2016. The final language changes include the following:

- Section 2: Definition has been modified as follows:
    - "Comparative group" means the applications which have been grouped for the same type of project in the same planning area OR STATEWIDE SPECIAL POPULATION GROUP and are being reviewed comparatively in accordance with the CON rules. Definition updated to include special population groups covered under the new addendum.
- Section 15(1)(d): Modified as follows:
    - There shall be the following minimum staff employed either on a full time basis or ACCESS TO on a consulting basis AS NEEDED. This will provide more flexibility to the provider.
- Addendum for Special Population Groups is being added for specific needs, i.e., developmentally disabled, geriatrics, and medical psychiatric. This will provide more access to beds for these specific hard to place patients.
- Other technical edits.

The revisions to the CON Review Standards for NH-HLTCU Beds and Addendum for Special Population Groups received final approval by the CON Commission on June 15, 2017 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective September 21, 2017. The final language changes include the following:

- Updated the Department name throughout the document.
- Section 2(1)(b): The Average Daily Census (ADC) adjustment factor definition was updated to apply a factor of 0.90 for all planning areas to reflect the overall change in occupancy and lengths of stay.
- Information contained in Appendix B will be moved to the Department website as opposed to being imbedded in the standard.
- Section 6: The high occupancy provisions were revised to be facility specific, not county, based on the current environment of shorter lengths of stay and managed care.
- Section 9: Language was added that clarifies requirements for a new entity with no prior NH-HLTCU history that is applying to acquire a NH-HLTCU.
- Section 10: The criteria for a Bariatric patient room has been updated and clarified.
- Section 14: Language was added to clarify that nursing home replacement will not be subject to comparative review if the new site is within the same planning area as the existing site. Reduced regulation provides facilities more opportunities for submitting an application versus the current three times a year.
- Appendices C and E were removed as they are no longer needed due to other changes in the standards.
- In the statewide pool for the needs of special population groups addendum, the requirements to initiate hospice beds were removed as they are no longer needed, and requirements to initiate and acquire Bariatric patient beds were added along with corresponding project delivery requirements as there is an increased need for this special population group.
- The method for adjusting and redistributing the number of beds available in the statewide pool for the needs of special population groups was revised.
- Other technical edits.

APPENDIX I - CERTIFICATE OF NEED COMMISSION

Suresh Mukherji, MD, CON Commission Chairperson
Thomas Mittlebrun, III, Vice-Chairperson
Denise Brooks-Williams
Gail J. Clarkson, RN, NHA
Tressa Gardner, DO (Replaced Kathleen Cowling, DO)
James B. Falahee, Jr., JD
Debra Guido-Allen, RN
Robert L. Hughes
Marc D. Keshishian, MD,
Melanie Lalonde (Replaced Jessica A. Kochin)
Luis A. Tomatis, MD

For a list and contact information of the current CON Commissioners, please visit our web site at **http://www.michigan.gov/con**.

STATUS REPORT FROM THE MRT SAC

To: CON Commission
From: Brian Kastner, MD
MRT SAC Chair
Date: December 6, 2018 CON Commission meeting
RE: MRT SAC update

The MRT SAC has met **five** times thus far: June 28, July 26, August 30, October 3, and November 1, 2018.
The CON gave two charges to the SAC to consider: treatment weightings and volume requirements. The SAC reviewed both at the first meeting. The SAC discussed the changing practice patterns that have contributed to lower utilization. In particular, the SAC noted that the trend toward delivering care in fewer treatment fractions (hypo-fractionation) has lowered the logistical and financial burden on patients and payers. The SAC approached the question of treatment weightings by first agreeing that weightings should reflect MRT utilization time. The SAC agreed to maintain a 15-minute base unit for the equivalent treatment visit (ETV) to both preserve consistency with previous standards and to simplify evaluation of the impact of any subsequently proposed volume standards. Secondly, we conducted a survey to solicit the standard or average time required to deliver treatments. Thereafter, the SAC revised the weightings to reflect the results of this survey.

The SAC began its review of the current volume requirements with the recognition that, for every one thousand ETVs, the MRT unit was actively treating one hour per clinic day throughout the year. In consideration of the Minimum volume, we observed that the current 8000 ETV minimum assumed 8-hour-per-day of active treatment, and we felt this to be an unreasonably high minimum volume. After thorough discussion of cost, quality and access, we agreed that any unit delivering at least 4000 ETV per year should be considered as meeting minimum volume. The SAC subsequently produced a consensus statement in this regard (see attached).

The SAC provided clarification to definitions regarding MR-guided radiotherapy and patient-specific quality assurance for stereotactic procedures. We also considered volume requirements for MRT replacement, initiation and expansion. The discussion regarding these volumes included express consideration of cost, quality and access. The SAC concluded that further consideration of changes to replacement, initiation and expansion volumes should await potential impact from implementation of the proposed changes to the weighting and minimum volume standards.

Interim Report
Psychiatric Beds and Services Workgroup Meeting
28 November 2018
Prepared by Laura Hirshbein, MD, PhD

Since the last interim report (on 9/18/18), the Psychiatric Beds and Services Workgroup has met twice more, on 17 October 2018 and 15 November 2018. More than 80 people from all over the state have attended one or more of the workgroup meetings thus far.

In our last two meetings, we heard a number of presentations to help us with more accurate details to help guide the group's recommendations.

- Paul Delamater walked the group through the current bed need methodology, and also showed us the mismatch between the bed projections and the actual usage in the last five years.
- Carolyn Watters and Krista Hausermann presented the Michigan Psychiatric Admission Denial Database project. The same patients seemed to generate a high number of denials – suggesting that there are some patient populations that present more challenges than others.
- Ken Deighton presented a survey of operational beds versus licensed beds. From his sample, there were more than 90% of licensed beds in use at the hospitals.
- Dr. George Mellos discussed some of the many challenges that face the state psychiatric hospitals and forensic center. He pointed out that not all psychiatric beds are equivalent.
- Lee Ann Odom presented a proposal to allow established psychiatric hospitals to open child/adolescent beds regardless of the bed need formula. To staff these proposed beds, facilities would have to have an agreement with an established child/adolescent facility for joint appointment of child psychiatrists for staffing. She noted that this could have implications for training of more child psychiatrists.
- A representative from MDHHS discussed the usage of the special pool beds that were approved two years ago. There appear to be many adult DD beds left, as well as significant numbers of med-psych beds (adult and child). The child DD beds are all spoken for.

Next steps:

- Paul Delamater is going to propose a new methodology to determine bed need (based on procedures used in the general acute care hospitals).
- Lee Ann Odom is going to work with a small group to suggest specific wording for her proposal about allowing for child/adolescent beds.
- I am going to lead a small group to look at the special pool beds and craft a proposal for special beds going forward.
- Next meeting scheduled for 13 December 2018.
- We expect to be able to complete the work, along with specific wording to answer the charges to the workgroup, after the meeting in January 2019.

CERTIFICATE OF NEED

4th Quarter Compliance Report to the CON Commission

October 1, 2017 through September 30, 2018 (FY 2018)

This report is to update the Commission on Department activities to monitor compliance of all Certificates of Need recipients as required by Section 22247 of the Public Health Code.

MCL 333.22247

(1) The department shall monitor compliance with all certificates of need issued under this part and shall investigate allegations of noncompliance with a certificate of need or this part.

(2) If the department determines that the recipient of a certificate of need under this part is not in compliance with the terms of the certificate of need or that a person is in violation of this part or the rules promulgated under this part, the department shall do 1 or more of the following:

(a) Revoke or suspend the certificate of need.

(b) Impose a civil fine of not more than the amount of the billings for the services provided in violation of this part.

(c) Take any action authorized under this article for a violation of this article or a rule promulgated under this article, including, but not limited to, issuance of a compliance order under section 20162(5), whether or not the person is licensed under this article.

(d) Request enforcement action under section 22253.

(e) Take any other enforcement action authorized by this code.

(f) Publicize or report the violation or enforcement action, or both, to any person.

(g) Take any other action as determined appropriate by the department.

(3) A person shall not charge to, or collect from, another person or otherwise recover costs for services provided or for equipment or facilities that are acquired in violation of this part. If a person has violated this subsection, in addition to the sanctions provided under subsection (2), the person shall, upon request of the person from whom the charges were collected, refund those charges, either directly or through a credit on a subsequent bill.

Activity Report

Follow Up: In accordance with Administrative Rules 325.9403 and 325.9417, the Department tracks approved Certificates of Need to determine if proposed projects have been implemented in accordance with Part 222. By rule, applicants are required to either implement a project within one year of approval or execute an enforceable contract to purchase the covered equipment or start construction, as applicable. In addition, an applicant must install the equipment or start construction within two years of approval.

Activity	4th Quarter	Year-to-Date
Approved projects requiring 1-year follow up	56	272
Approved projects contacted on or before anniversary date	21	179
Approved projects completed on or before 1-year follow up	38%	
CON approvals expired	27	118
Total follow up correspondence sent	131	705
Total approved projects still ongoing	351	

Compliance: In accordance with Section 22247 and Rule 9419, the Department performs compliance checks on approved and operational Certificates of Need to determine if projects have been implemented, or if other applicable requirements have been met, in accordance with Part 222 of the Code.

- The Department has completed statewide compliance reviews for Neonatal Intensive Care Unit (NICU) beds, Special Care Nursery (SCN) services, Open Heart Surgery (OHS) services, and Urinary Shockwave Lithotripsy (UESWL) services utilizing 2016 CON Annual Survey data. After evaluating the annual survey data, review standards' requirements, and responses to additional questionnaire, the Department has identified the CON approved facilities for compliance investigations. The Department recently completed compliance conference calls with each of these identified facilities and is in the process of finalizing settlements agreements and other compliance action plans with each of these identified facilities. The detailed finding of the statewide compliance reviews will be reported to the CON Commission in a separate report at a later date.
- McLaren Oakland – The Department was notified that McLaren Oakland completed renovations of existing space on the 6th floor Oncology unit of the hospital at McLaren Oakland without Certificate of Need (CON) approval. The facility was required to submit a written corrective action plan establishing a process to ensure that CON covered services, equipment, covered capital expenditure projects needing approval prior to operation are properly approved and should involve management level education about the CON process and requirements. The facility was required to pay a civil fine of $22,000.

Source: CON Evaluation Section, Michigan Department of Health and Human Services.

CERTIFICATE OF NEED

4th Quarter Program Activity Report to the CON Commission

October 1, 2017 through September 30, 2018 (FY 2018)

This quarterly report is designed to assist the CON Commission in monitoring and assessing the operations and effectiveness of the CON Program Section in accordance with Section 22215(1)(e) of the Public Health Code, 1978 PA 368.

Measures

Administrative Rule R325.9201 requires the Department to process a Letter of Intent within 15 days upon receipt of a Letter of Intent.

Activity	4th Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	88	N/A	371	N/A
Letters of Intent Processed within 15 days	88	100%	370	99%
Letters of Intent Processed Online	88	100%	371	100%

Administrative Rule R325.9201 requires the Department to request additional information from an applicant within 15 days upon receipt of an application, if additional information is needed.

Activity	4th Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	62	N/A	296	N/A
Applications Processed within 15 Days	62	100%	295	99%
Applications Incomplete/More Information Needed	43	69%	213	71%
Applications Filed Online*	62	100%	279	100%
Application Fees Received Online*	23	37%	67	24%

* Number/percent is for only those applications eligible to be filed online, potential comparative and comparative applications are not eligible to be filed online, and emergency applications have no fee.

Administrative rules R325.9206 and R325.9207 require the Department to issue a proposed decision for completed applications within 45 days for nonsubstantive, 120 days for substantive, and 150 days for comparative reviews.

Activity	4th Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	32	100%	174	100%
Substantive Applications	41	100%	107	100%
Comparative Applications	0	N/A	0	N/A

Note: Data in this table may not total/correlate with application received table because receive and processed dates may carry over into next month/next quarter.

Measures – continued

Administrative Rule R325.9227 requires the Department to determine if an emergency application will be reviewed pursuant to Section 22235 of the Public Health Code within 10 working days upon receipt of the emergency application request.

Activity	4th Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Emergency Applications Received	0	N/A	0	N/A
Decisions Issued within 10 workings Days	0	N/A	0	N/A

Administrative Rule R325.9413 requires the Department to process amendment requests within the same review period as the original application.

Activity	4th Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	13	100%	75	100%

Section 22231(10) of the Public Health Code requires the Department to issue a refund of the application fee, upon written request, if the Director exceeds the time set forth in this section for a final decision for other than good cause as determined by the Commission.

Activity	4th Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	4th Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	62	N/A	237	N/A
FOIA Requests Processed on Time *	62	100%	237	100%
Number of Applications Viewed Onsite	0	N/A	0	N/A

FOIA – Freedom of Information Act.

*Request processed within 5 days or an extension filed.

Source: CON Evaluation Section, Michigan Department of Health and Human Services.

STATE OF MICHIGAN
DEPARTMENT OF ATTORNEY GENERAL

BILL SCHUETTE
ATTORNEY GENERAL

M E M O R A N D U M

November 27, 2018

TO: James Falahee
CON Commission Chair

FROM: Carl Hammaker
Assistant Attorney General
Corporate Oversight Division

RE: Legal Report for the September 20, 2018 Commission Meeting

We currently have two pending cases in the Michigan Administrative Hearing System.

On July 10, 2018, the Department issued its decision to expire CON 13-0375. CON 13-0375 was an approved project to make a change to the bed capacity at the Hickory Ridge of Temperance facility by adding 20 nursing home beds into a newly constructed addition. The matter is set for a status conference with the Administrative Law Judge on January 29, 2018.

On October 5, 2018, the Department issued a proposed decision to disapprove CON Application No. 18-0050 to begin operation of a new nursing home, Regency at East Ann Arbor. A telephone prehearing conference is scheduled for November 29, 2018.

In addition to this case, we continue to work with DHHS staff to assist in developing standards and providing legal advice on various matters.

CJH/
Cc: Elizabeth Nagel
Joseph Potchen

CURRICULUM VITAE

JAY S. DWORKIN, Ph.D.
Email: dworkin.fonar@icloud.com

EDUCATION

University of Michigan at Ann Arbor
Ph.D., Physics (1983)
- Co-authored 15 published experimental high-energy elementary particle physics research papers.
- Ph.D. Dissertation: *A High Statistics Study of Lambda Beta Decay*
- Obtained the world's largest sample of this rare nuclear decay process during research at the *Fermi National Accelerator Laboratory* in Batavia, IL.
- Designed, built and calibrated an innovative x-ray detector for an intricate experiment apparatus used to detect and study sub-atomic particles.

W. Averell Harriman School for Management and Policy
State University of New York at Stony Brook
M.S., Management (1993)
Awarded the *1993 Thesis Prize* for "Conner Peripherals, Inc.: An Equity Analyst's View"
- Constructed a spreadsheet-based valuation model discounting free cash flow forecasts.
- Strategically assessed the competitive environment in the PC disk drive industry.

Brown University, Providence,RI
B.S., Physics (1975)

WORK EXPERIENCE

FONAR Corporation Melville, Long Island, New York (1984-present)
Scientific, product development and marketing positions related to both the design, manufacture and service of the company's MRI equipment and the operations of its subsidiary Health Management Company of America that provides non-medical management services for medical diagnostic imaging centers.
Senior Physicist, Magnetic Resonance Imaging (2002-present)
Product Marketing Manager (1994-present)
Research Scientist, Systems Engineer (1984-1994)

ACADEMIC FACULTY APPOINTMENTS

- Clinical Assistant Professor of Radiology, SUNY Downstate Medical Center, Brooklyn NY (2000-2002)
- Postdoctoral Scholar, Department of Physics, University of Michigan at Ann Arbor (1983-1984)

ADVISORY ACTIVITY

Advisory Board (1996-1999) Harriman School for Management and Policy, SUNY at Stony Brook *Developed recommendations for the President's Office to define the Business School's objectives*

TEXTBOOKS

- *The Craniocervical Syndrome and MRI*, FW Smith, MD and JS Dworkin, PhD (Eds.), Karger (2015)
- Co-author of the chapter "Positional and Kinetic Spin Imaging" in *Magnetic Resonance Imaging, 3rd Edition*, R. Edelman, MD, J. Hesselink, MD, M. Zlatkin, MD and J. Crues, III, MD (Eds.), Elsevier Science (2006)
- Co-author of the chapter "Upright, Weight-bearing, Dynamic-kinetic MRI of the Spine: pMRI/kMRI" in *Spinal Restabilization Procedures: Diagnostic and Therapeutic Aspects of Intervertebral Fusion Cages, Artificial Discs and Mobile Implants*, D. Kaech, MD, J.R. Jinkins, MD (Eds.), Elsevier Science (2002)
- Author of the chapter "The Technology and Potential of Open Magnetic Resonance Imaging"in *Open Field Magnetic Resonance Imaging*, D. Groenemeyer, MD, R. Lufkin, MD (Eds.), Springer-Verlag (2000)
- Co-author of the chapter "A Proposed New Magnet Design for MR-Guided Surgery at 0.6 Tesla" in *Interventional MRI,* R. Lufkin, MD (Editor), Mosby (1999)

PROFESSIONAL SOCIETY PUBLICATIONS

- "Upright Weight-Bearing, Dynamic-Kinetic MRI of the Spine (pMRI/kMRI): Overview of first results with the Stand-Up MRI"; Co-author of an article in *Argos Spine News* 8:16-21 (2003)
- "A Survivor's Guide to MRI Performance Specifications"; Author of an article in The Clinical Magnetic Resonance Society *Vision* 3(4) (1997)

EDUCATIONAL AND MARKETING SEMINARS

- "MRI Equipment: Present Capabilities and Future Directions", *Corporate Technology Forum*, MRI National Symposium, Las Vegas, NV [Hosted by Educational Symposia, Inc.] (2006)
- "The Future of Magnetic Resonance Imaging (MRI)", *Life Sciences Industry Summit* hosted by the Long Island Life Sciences Initiative and the Center for Biotechnology, Melville, NY (2006)
- "How We Use Magnetic Fields in MRI", *Conference Faculty,* Basic Concepts of Open MRI for Technologists, White Plains, NY [Hosted by Northwest Imaging Forums] (2000)
- "Technology Marketing and Management", *Guest Lecturer,* Executive Technology Management Program, Harriman School for Management and Policy, SUNY Stony Brook (1999)
- "Performance Specifications in Magnetic Resonance Imaging", *Orthopedic and Neuroradiology Review,* Brisbane, Australia [Hosted by MRI Education Foundation, Inc.] (1998)
- "Computer-Based Image Management and Telecommunications in Radiology", *High-Technology Health Care Congress*, Bochum, Germany (1997)

SELECTED SCIENTIFIC PUBLICATIONS

1. *Upright, Weight-bearing, Dynamic-kinetic MRI of the Spine: Initial Results*, JR Jinkins, JS Dworkin and RV Damadian, European Radiology (2005) 15: 1815-1825
2. *Upright, Weight-bearing, Dynamic-kinetic Magnetic Imaging of the Spine: Review of First Clinical Results,* JR Jinkins et. al., J Hong Kong Coll Radiol 6: 55-747 (2003)
3. *High-statistics measurement of g(A)/g(V) in Lambda Beta Decay*, J. Dworkin et al., Physical Review D, Vol. 41, No. 3, 780, (1990)
4. *Branching Ratio and Asymmetry for the decay Cascade-Zero to Lamda Gamma*, C. James et al., Physical Review Letters, Vol. 64, No. 8, 843 (1990)
5. *Automated MR Imaging Protocols for Improved Patient Throughput*, R. Lufkin et al., Comp. Medical Imaging and Graphics, Vol. 12, No. 2, 85 (1988)
6. *New Measurements of Properties of the Omega Minus Hyperon*, K.B. Luk et al., Physical Review D, Vol. 38, No. 1, 19 (1988)
7. *Proton NMR Imaging of Green State Ceramics*, L. Welsh et al., Review of Progress in Quantitative Non-Destructive Evaluation, Edited by D. Thompson, Vol. 6A, Plenum (1987)
8. *Electron Identification Using a Synchrotron Radiation Detector*, J.S. Dworkin et al., Nuclear Instruments and Methods in Physics Research, A247, 412 (1986)

DETAILED WORK EXPERIENCE

- Write and deliver lectures at educational and medical seminars
- Publish articles both in textbooks and peer-reviewed scientific journals
- Shape objectives and develop sales material for major trade shows
- Conceive and program multimedia computer presentations for users and marketing representatives
- Build and maintain strong business relationships with key users and referring physicians
- Design product brochures and provide content for online marketing support
- Assess technology advances and determine product performance specifications
- Conduct site visits and product demonstrations for clients in U.S. and abroad
- Provide detailed product training, competitive analysis and marketing support for the capital equipment direct salesforce, international distributors and diagnostic imaging center marketers
- Directed software programmers and engineers adding new imaging features to the MRI scanner
- Designed and calibrated imaging techniques using customized software tools
- Wrote software for pattern recognition and statistical analysis of experimental data
- Directed the activities of a 10-physicist research team at the Fermi National Accelerator Laboratory

The Clinical Significance of the FONAR Upright® MRI

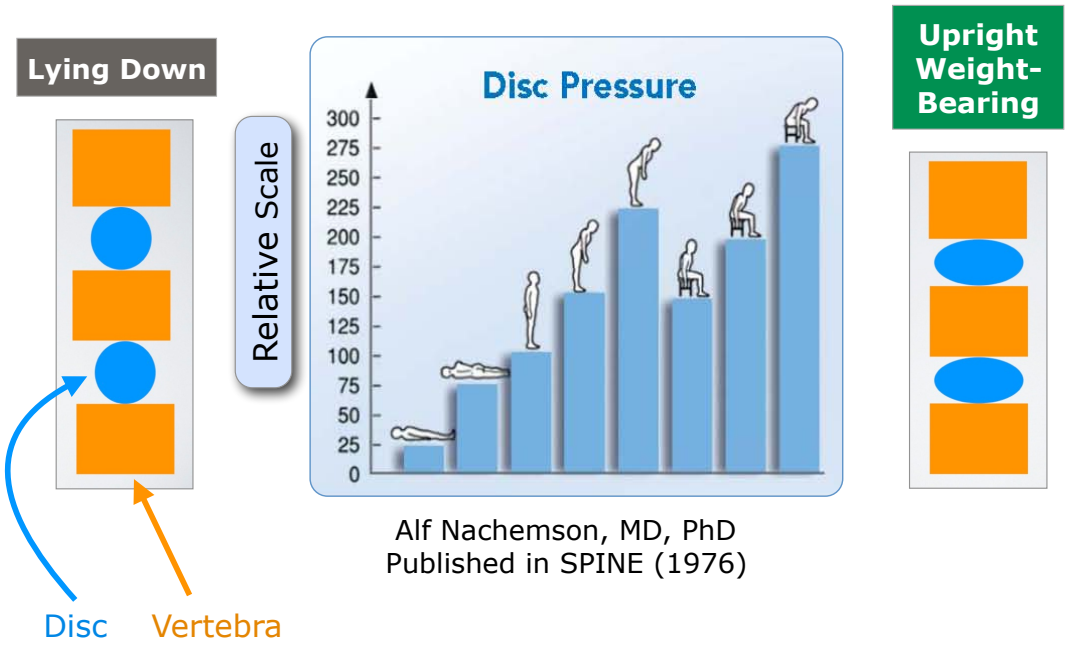
Rotate the bed from upright to recumbent and compare MRI scans in different patient positions

Acquire MRI scans in both flexion & extension positions since there is nothing in front of the patient's face

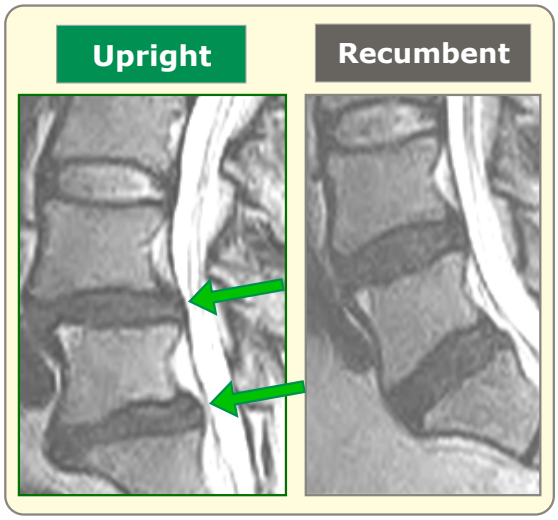
Unique Benefits:
- Weight-bearing MRI
- Multi-position MRI

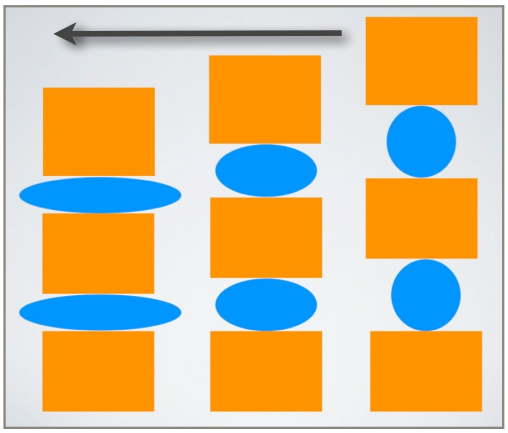
The Consequences of Gravity

Note the significant increase in the measured spinal disc pressure when the patient is NOT lying down



Alf Nachemson, MD, PhD
Published in SPINE (1976)





There is considerable evidence that the Upright Weight-Bearing MRI provides medical benefits that are **not duplicated** by any other MRI

- Patient positioning plays a critical role in detecting clinically significant pathology
- Recumbent-only imaging can underestimate the maximum degree of pathology
- Peer-reviewed publications demonstrate the impact on treatment

"The dominant motions at both the lower cervical and entire lumbar spine, where most clinical pathology occurs, are flexion-extension."

~ AMA Guide to the Evaluation of Permanent Impairment ~

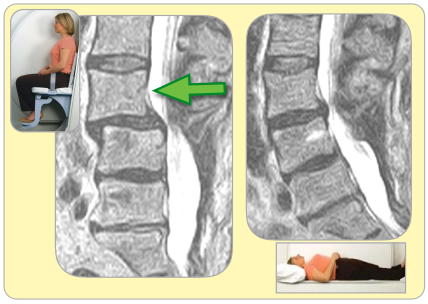
Flexion

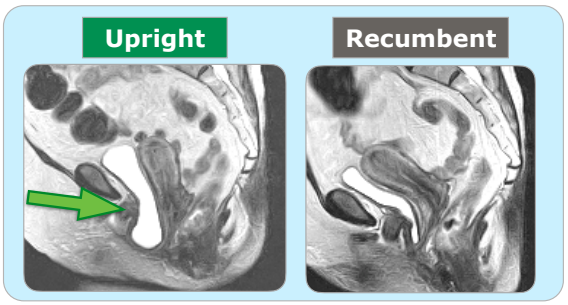
Extension

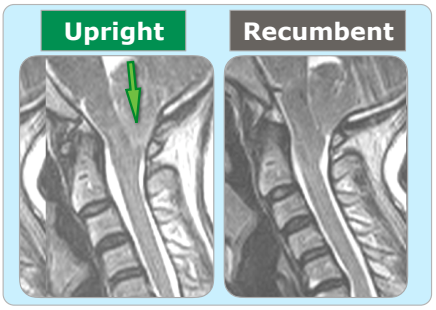
You need the Upright MRI to see the **pathology highlighted in green**

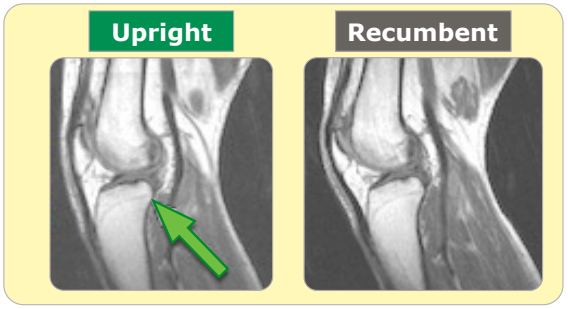
Compare the same patient in different positions on the same day in the same MRI scanner.

Patient positioning plays a critical role in detecting clinically significant pathology.





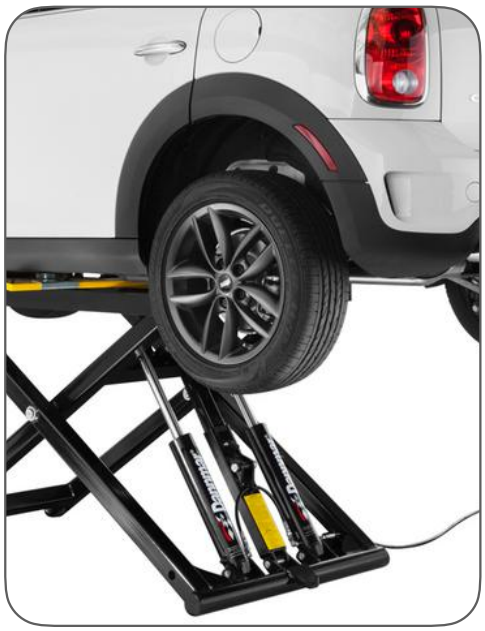




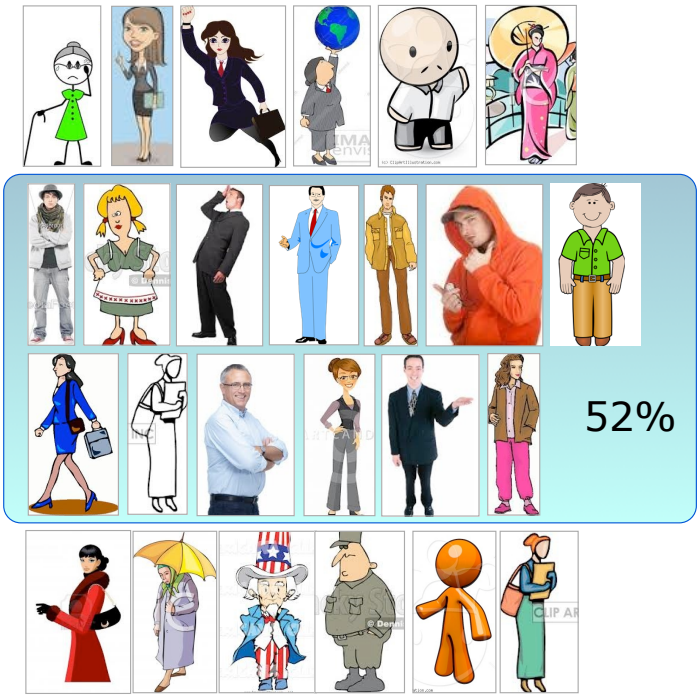
You need to make use of gravity to see the **pathology highlighted in green**

A useful analogy provided by an orthopedic surgeon at a CON hearing: *What's the best way to diagnose whether or not you have a flat tire?*

Position-dependent tire compression



Twenty-five (25) chronic low back pain & sciatica patients with prior "negative" recumbent-only MRIs …



"Upright MRI in the Seated Position Increases Insight into Degenerative Disc Disease"
Clinical MRI (2006)

What percentage showed abnormalities in one or more of the upright positions, and still nothing in their recumbent position?

Each of these 13 patients had successful surgery and six months later they remained symptom-free

A change in the severity of the malformation: 8-Surgery

"She saw her mother and father come in and burst into tears. I can see, she sobbed, I can see."

The bottom of the cerebellum extended nine millimeters into the spinal canal, compressing the brain and nerve tissue

1-Several eye doctors
"emotional blindness"
2-Neuro-Opthamologist
Nystagmus
Inner ear
Cerebellum (MRI)
no clot
no mass
Chiari malformation: five millimeter sliver of cerebellum visible below the skull
Cause or incidental?
3-Neurosurgeon#1
Too small; probably not related to Ehlers-Danlos Syndrome
4-Neurologist
Don't know
5-Neurosurgeon#2
Ulrich Batzdorf, MD @UCLA; suggests Chiari can be complicated by E.D.S.
6-Pediatric Neurosurgeon
7-Neurosurgeon#2
Orders Upright MRI

jerky, blurred vision and light sensitivity
terrible headaches
Symptoms
weakness and pain in her legs

https://www.nytimes.com/2018/05/01/magazine/why-was-her-vision-jerky-and-blurry-if-there-was- nothing-wrong-with-her-eyes.html

Magazine

Why Was Her Vision Jerky and Blurry if There Was Nothing Wrong With Her Eyes?

Diagnosis

By Lisa Sanders, M.D. May 1, 2018

The young woman rubbed her eyes. The numbers and letters on her computer screen jumped erratically. So did the world around her. This had happened before, but late at night when she was tired, never in the middle of the day. The light from the screen suddenly seemed too bright. And her headache, the one that was always present these days, tightened from a dull ache to a squeezing pressure on the back of her head and neck. Nearly in tears from pain and frustration, the 19-year-old called her mother. She couldn't see; she couldn't drive. Could her mother pick her up from work?

The problems with her eyes began in grade school. Two years earlier, she nearly went blind. All she could see on the left was a rim of light. Everything else was blocked by a big black spot. And then a black dot appeared in her right eye as well. Her parents took her to see many eye doctors, only to be told that there was nothing wrong. One doctor told them that she had "emotional blindness." The young woman's vision somehow got a lot better on its own, and though the black dot still obstructed some of her vision, for the last eight months she'd been able to drive — so important in this small mountain town an hour north of San Diego.

Problems in the Brain?

Now she couldn't see for what seemed like a different reason. The young woman's mother arranged for her to go to San Diego to see a neuro- ophthalmologist — a doctor who specializes in vision problems that originate in the brain. When they got to the office, though, the young woman's vision and headache had returned to their imperfect but baseline state. She told the doctor that her symptoms were least intrusive in the morning; standing and walking seemed to make everything worse. Come back later, the doctor instructed. Mother and daughter walked around and shopped.

When a couple of hours later the daughter's eyes started jumping and her headache worsened, they hurried back to the office.

The doctor took one look at the young woman's eyes and told her she had nystagmus. It's a failure in the parts of the brain that allow our eyes to stay focused when the object being observed or the observer moves. Problems in the inner ear — where head position is perceived — are the most common cause of nystagmus, usually accompanied by vertigo. Persistent nystagmus is worrisome because it can indicate abnormalities in other parts of the brain, primarily the cerebellum — the chief coordinator of all movement. The doctor sent the patient to

the Sharp Memorial Hospital emergency room for an M.R.I.; it would reveal if a clot or mass in the brain was causing the nystagmus.

There was no clot, no mass, but there was an abnormality. At the lowest part of the young woman's brain, where the spinal cord emerges, a tiny sliver of cerebellum was visible just below the skull. A little slippage of brain tissue into the spinal column can be normal as long as it is no more than five millimeters below the skull; anything more is considered pathological. Hers was right at five millimeters.

How Serious Is Brain Slippage?

This downward displacement of the brain, known as a Chiari malformation (after the 19th-century Austrian pathologist who identified the types of malformations) is a common abnormality. Imaging studies suggest that it may be present in one in every 200 of us, and many times it causes no symptoms at all. For these patients, the discovery of the Chiari malformation is usually accidental — noted on a scan obtained for some other reason.

The symptoms, for those who get them, are caused by compression of the brain tissue and nerves into the small space of the spinal canal. The specific symptoms will depend on what is being crushed. The most common is headache, usually located at the back of the head and down the neck, but a wide variety of other symptoms can occur, ranging from weakness, fainting and difficulty swallowing to hearing loss, curvature of the spine and insomnia. The question for patients with small Chiari malformations, like this young woman's, is whether it is the cause of her symptoms or an incidental finding. It's an important determination, because if the malformation is the cause, then surgery is needed to create room for the brain.

The young woman made an appointment with a neurosurgeon, but before she could see him, she awoke one day too weak to get out of bed. Her legs muscles refused to hold her up. When helped to her feet, bolts of pain shot from the back of her head down her spine into her legs. Her mother took her back to the E.R. at Sharp Memorial, where she was admitted.

Were the weakness, pain and nystagmus caused by the crowding in her brain? The neurosurgeon reviewed her scan. He said he did not think the tiny malformation visible on the M.R.I. could cause any of her symptoms; it was simply too small. She did need to be evaluated by a neurologist. That doctor was not sure what was going on, either.

A Different Ailment

The parents mentioned to the neurosurgeon that the year before, their daughter was diagnosed with Ehlers-Danlos syndrome (E.D.S.), an inherited disorder of the connective tissues that causes — in its most benign form — hypermobility in the joints and unusually stretchy skin. It can also cause repeated joint dislocations and injuries of skin, muscle and blood vessels. She already had four shoulder operations to stabilize the joints and prevent additional dislocations. Could the headaches and the nystagmus be related in some way to her E.D.S.? the parents asked. Probably not, the neurosurgeon told them. The patient's mother scoured the internet for a link between these two disorders. She came across several papers referring to a surgeon, Dr. Ulrich Batzdorf in Los Angeles, who described Chiari as a disorder that can be complicated by E.D.S. She called his office and was referred to Dr. Aria Fallah, a pediatric neurosurgeon at U.C.L.A. Mattel Children's Hospital.

A Standing Test

Fallah listened carefully as the young woman and her parents described her horrible past weeks — the jerky, blurred vision, the light sensitivity, the terrible headaches and now the weakness and pain in her legs.

After examining the young woman, Fallah then reviewed her M.R.I. Her symptoms were classic for a Chiari malformation, but her scan was not. While size alone did not determine how significant the symptoms would be, the bit of tissue slipping into the spinal cord on her M.R.I. seemed too small to cause the symptoms she described.

Following their appointment, Fallah took the case to Batzdorf, a mentor to him and a surgeon widely considered a "guru" in Chiari malformations and their repair. Batzdorf recommended an

M.R.I. done while the patient was standing upright. The patient had noticed that her symptoms got worse while standing; perhaps that reflected a change in the severity of the malformation. He'd certainly seen this in the past with some patients who also had E.D.S. He wasn't sure why.

Standing M.R.I.s are not widely available, but Batzdorf knew of one in a facility nearby. These images of the malformation were different. The bottom of the cerebellum extended nine millimeters into the spinal canal. And the compression of brain and nerve tissue was clearly visible in this scan.

Necessary Surgery

The patient was scheduled for surgery the next month. It was late morning when the young woman was taken to the recovery room after the procedure. The first thing she noticed when she woke was that her jiggling, blurred vision was now stilled and sharp. The black dot was also gone. The light no longer stabbed her eyes. She saw her mother and father come in and burst into tears. I can see, she sobbed. I can see.

It took the young woman many months of physical therapy to get her strength back. She will start college this summer. She's planning to be a physical therapist.

Lisa Sanders, M.D., is a contributing writer for the magazine and the author of "Every Patient Tells a Story: Medical Mysteries and the Art of Diagnosis." If you have a solved case to share with Dr. Sanders, write her at Lisa.Sandersmd@gmail.com.

Note: New or revised standards may include the provision that make the standard applicable, as of its effective date, to all CON applications for which a final decision has not been issued.

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

Attachment J

	2018						2019					
	July	August	September	October	November	December	January	February	March	April	May	June
Commission Meetings			Meeting			Meeting	Special Meeting		Meeting			Meeting
Air Ambulance Services				Public Comment Period			Discussion/ Report					
Bone Marrow Transplantation (BMT) Services				SAC Nomination & Selection Period				Discussion	Draft Language Presented			
Cardiac Catheterization Services	Public Hearing		Report/ Final Action									
Computed Tomography (CT) Scanner Services				Public Comment Period			Discussion/ Report					
Megavoltage Radiation Therapy (MRT) Services/Units		SAC Meeting		SAC Meeting	SAC Meeting				Report/Draft Language Presented/ Potential Proposed Action	Public Hearing		Report/ Final Action
Neonatal Intensive Care Services/Beds (NICU)				Public Comment Period			Discussion/ Report					
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups				Public Comment Period			Discussion/ Report					
Open Heart Surgery (OHS)	Public Hearing		Report/ Final Action									

	2018						2019					
	July	August	September	October	November	December	January	February	March	April	May	June
Psychiatric Beds and Services	Workgroup Meeting	Workgroup Meeting	Workgroup Meeting	Workgroup Meeting	Workgroup Meeting	Workgroup Meeting	Workgroup Meeting					
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units				Public Comment Period			Discussion/ Report					
New Medical Technology Standing Committee	Department Monitoring				Department Monitoring				Department Monitoring			
2-year Report to Joint Legislative Committee (JLC) – 1/1/19			Review Draft Report			Approve Report						
FY2018 CON Annual Report							Present Report to Commission					

For Approval December 6, 2018 The CON Commission may revise this work plan at each meeting. For information about the CON Commission work plan or how to be notified of CON Commission meetings, contact the Michigan Department of Health and Human Services (MDHHS), Policy, Planning & Legislative Services, Office of Planning, 5th Floor South Grand Bldg., 333 S. Grand Ave., Lansing, MI 48933, 517-335-6708, www.michigan.gov/con.

SCHEDULE FOR UPDATING CERTIFICATE OF NEED (CON) STANDARDS EVERY THREE YEARS*

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	June 2, 2014	2019
Bone Marrow Transplantation Services	September 29, 2014	2021
Cardiac Catheterization Services	September 14, 2015	2020
Computed Tomography (CT) Scanner Services	December 9, 2016	2019
Heart/Lung and Liver Transplantation Services	September 28, 2012	2021
Hospital Beds	November 28, 2018	2020
Magnetic Resonance Imaging (MRI) Services	October 21, 2016	2021
Megavoltage Radiation Therapy (MRT) Services/Units	September 14, 2015	2020
Neonatal Intensive Care Services/Beds (NICU)	December 9, 2016	2019
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	March 20, 2015	2019
Open Heart Surgery Services	June 2, 2014	2020
Positron Emission Tomography (PET) Scanner Services	September 14, 2015	2020
Psychiatric Beds and Services	December 9, 2016	2021
Surgical Services	November 17, 2017	2020
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	May 29, 2018	2019

*Pursuant to MCL 333.22215 (1)(m): "In addition to subdivision (b), review and, if necessary, revise each set of certificate of need review standards at least every 3 years."

**A Public Comment Period will be held in October prior to the review year to determine what, if any, changes need to be made for each standard scheduled for review. If it is determined that changes are necessary, then the standards can be deferred to a standard advisory committee (SAC), workgroup, or the Department for further review and recommendation to the CON Commission. If no changes are determined, then the standards are scheduled for review in another three years.