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

Thursday, February 8, 2018

South Grand Building
333 S. Grand Ave
1st Floor, Rooms 1K & 1L
Lansing, MI 48933

APPROVED MINUTES

I. Call to Order

Chairperson Mukherji called the meeting to order at 9:30 a.m.

A. Members Present:

Suresh Mukherji, MD, Chairperson
Thomas Mittelbrun, Vice-Chairperson
Denise Brooks-Williams
Gail J. Clarkson, RN
Tressa Gardner
Debra Guido-Allen, RN
Robert Hughes
Melanie LaLonde

B. Members Absent:

James B. Falahee, Jr., JD
Marc Keshishian, MD
Luis Tomatis, MD

C. Department of Attorney General Staff:

Joseph Potchen

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

Tulika Bhattacharya
Amber Myers
Beth Nagel
Tania Rodriguez

II. Review of Agenda

Motion by Commissioner Gardner, seconded by Commissioner Guido-Allen, to approve the agenda as presented. Motion carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of December 7, 2017

Motion by Commissioner Mittlebrun, seconded by Commissioner Clarkston, to approved the minutes as presented. Motion carried.

V. Bone Marrow Transplantation (BMT) Services – October 6, 2017 Public Comment Period Summary & Report

Ms. Rogers gave an overview of the public comment period summary (Attachment A) and the Department's recommendations.

A. Public Comment

1. Malcolm Henoch, MD, Beaumont Health (see Attachment B)
2. Barbara Bressack, Henry Ford Health System (HFHS)
3. Joseph Uberti, MD, Karmanos
4. David Walker, Spectrum Health
5. Gregory Yanik, MD, University of Michigan
6. Eric Fischer, DMC Children's Hospital of Michigan

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner Mittlebrun to open the standards for the limited purpose to allow for the change for infusion of cell therapy products including chimeric antigen receptor T-cells (CAR-T) to be limited to BMT services, i.e., remove "stem" from definition of "BMT service." The Department will bring back language to a future meeting. Motion carried in a vote of 7 - Yes, 1 - No, and 0 - Abstained.

VI. Heart/Lung and Liver Transplantation (HLLT) Services – October 6, 2017 Public Comment Period Summary & Report

Ms. Rogers gave an overview of the public comment period summary (Attachment C) and the Department's recommendations.

A. Public Comment

1. Barbara Bressack, HFHS
2. David Walker, Spectrum Health

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Gardner, seconded by Commissioner Clarkson to make no changes to the standards and move forward to the next review period in 2021. Motion carried in a vote of 8 - Yes, 0 - No, and 0 - Abstained.

VII. Magnetic Resonance Imaging (MRI) Services – October 6, 2017 Public Comment Period Summary & Report

Ms. Rogers gave an overview of the public comment period summary (Attachment D) and the Department's recommendations.

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Clarkson, seconded by Commissioner Guido-Allen to accept the Department's recommendation as presented to continue regulation and review the standard again in 2021. Motion carried in a vote of 8 - Yes, 0 - No, and 0 - Abstained.

VIII. Psychiatric Beds and Services – October 6, 2017 Public Comment Period Summary & Report

Ms. Rogers gave an overview of the public comment period summary (Attachment E) and the Department's recommendations.

A. Public Comment

1. Lee Ann Odom, Beaumont Health
2. David Walker, Spectrum Health

3. Traci Dietz, HFHS

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Mittlebrun, seconded by Commissioner Gardner to accept the Departments recommendation to create a Standard Advisory Committee (SAC) to review the issues identified by the Department in the summary report; delegate to the chairperson to draft the charge and seat the SAC. Motion carried in a vote of 8 - Yes, 0 - No, and 0 - Abstained.

IX. Megavoltage Radiation Therapy Services – Proton Beam Therapy

Reshma Jagsi, MD, DPhil, University of Michigan Health System provided a presentation (Attachment F).

Craig Stevens, MD, Beaumont Hospital, provided a presentation (Attachment G).

A. Public Comment

1. Arlene Elliott, Arbor Advisors, on behalf of Mary Boyd, Trinity Health
2. Salim Siddiqui, HFHS
3. Marlene Hendershot, Sparrow Health System
4. Sean Gehle, Ascension Health
5. Thomas Lunni, Beaumont Health
6. Tony Denton, University of Michigan

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Guido-Allen, seconded by Commissioner Hughes to make no changes to the proton beam therapy requirements, but open the standard for a limited review of the volumes and weights requirements by a SAC; the charge will be drafted for this specific purpose; and seating of the SAC is delegated to the chairperson. Motion carried in a vote of 8 - Yes, 0 - No, and 0 - Abstained.

X. FY 2017 CON Annual Activity Report

Ms. Bhattacharya gave an overview of the report (Attachment H).

Ms. Bhattacharya thanked her staff for their work.

XI. Public Comment

1. David Walker, Spectrum Health

XII. Review of Commission Work Plan

Ms. Rogers provided an overview of the changes to the Work Plan (Attachment I).

A. Commission Discussion

Discussion followed.

B. Commission Action

Motion by Commissioner Mittlebrun, seconded by Commissioner Hughes to accept the Work Plan as discussed. Motion carried in a vote of 8 - Yes, 0 - No, and 0 - Abstained

XIII. Future Meeting Dates – March 15, 2018, June 14, 2018, September 20, 2018, & December 6, 2018

XIV. Adjournment

Motion by Commissioner Clarkson, seconded by Commissioner Mittlebrun, to adjourn the meeting at 11:52 a.m. Motion Carried in a vote of 8 - Yes, 0 - No, and 0 - Abstained.

MDHHS Recommendations for CON Standards Scheduled for 2018 Review

Bone Marrow Transplantation (BMT) Services Standards			
Department Recommendations: The Department continues to urge the Commission to either deregulate or develop a needs-based methodology for this service.			
Identified Issues	**Issue Recommended for Substantive Review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Deregulate BMT Services or develop a need-based methodology	Yes.	The Commission as a whole should review these standards as an agenda item at one or more of its regularly scheduled meetings or at one or more special Commission meetings.	Department Comment: Previously, the Department, SACs, and workgroups have reviewed this and provided recommendations to the Commission. It is the Department's recommendation that if the Commission wants to make changes to this standard, then the Commission as a whole is best suited to review the issues and pursue a course of action.
Revise the definition of "BMT service" to specifically address an emerging therapy approved by the Food and Drug Administration (FDA) on August 30, 2017. Kymriah® (tisagenleuleucel) is now approved for the treatment of acute lymphoblastic leukemia (ALL) in children and young adults. Modifying the definition will allow for infusion of cell therapy products, including CAR-T cells.	Yes, if continued regulation.	The Commission as a whole should review this recommendation as an agenda item at one or more of its regularly scheduled meetings or at one or more special Commission meetings.	Department Comment: This recommendation would restrict this new therapy exclusively to only the BMT programs currently in existence, which are capped in the current standard. This could have access to care and quality of care implications that should be addressed prior to making this change to the definition of BMT.
Other technical edits by the Department if needed.			Department Comment: None identified

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "…review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the

established review schedule on the Commission Work Plan, the BMT Services Standards are scheduled for review in calendar year 2018.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 6 - 20, 2017. Testimony was received from six (6) organizations and is summarized as follows:

1. *Dennis McCafferty, The Economic Alliance for Michigan (EAM)*
    - EAM member organizations are not convinced that allowing additional BMT programs in the near suburbs of Detroit would result in improved access and increased utilizations of this service.
    - EAM states that autologous focused programs would drain the support staff and financial resources of existing BMT programs resulting in jeopardizing the existing high levels of staff competencies and the high quality of services.

2. *Carolyn Wilson, RN, MBA, Beaumont Health*
    - Beaumont Health supports deregulation of BMT services for the following reasons:
        - No data to support the current cap and no need methodology.
        - The Department has supported deregulation for several years.
        - The Department, at the Commission's request, developed language that removed the cap and established additional quality related requirements that would have limited number of new programs that could be approved. The Commission took no action and left the cap in place.
        - Only seven states regulate BMT services and none have a cap.

3. *Robert Riney and Steven Kalkanis, MD, Henry Ford Health System (HFHS)*
    - Supports continued regulation of BMT services and recommends no changes at this time.

4. *Justin Klamerus, MD, MMM and Joseph Uberti, MD, PhD, Karmanos Cancer Institute*
    - Supports continued regulation of BMT Services and recommends a workgroup be formed to specifically address an emerging therapy approved by the Food and Drug Administration (FDA) on August 30, 2017. Kymriah® (tisagenleuleucel) is now approved for the treatment of acute lymphoblastic leukemia (ALL) in children and young adults. Karmanos is asking the CON Commission to amend the regulations defining BMT services to incorporate infusion of cell therapy products, including CAR-T cells. This can be done by modifying the definition of "BMT service" by removing the word stem as follows: "BMT service means the transplantation of proliferating hematopoietic ~~stem~~ cells essential to the survival of a patient derived from the bone marrow, the peripheral circulation, cord blood, or any other source."

5. *Stephanie Williams, MD, Spectrum Health*
    - Supports continued regulation of BMT services and recommends no changes at this time.

6. *David Spahlinger, MD and Gregory Yanik, MD, University of Michigan Medicine*
    - Supports continued regulation of BMT Services and recommends a workgroup be formed to specifically address an emerging therapy approved by the Food and Drug Administration (FDA) on August 30, 2017. Kymriah® (tisagenleuleucel) is now approved for the treatment of acute lymphoblastic leukemia (ALL) in children and young adults. Karmanos is asking the CON Commission to amend the regulations defining BMT services to incorporate infusion of cell therapy products, including CAR-T cells. This can be done by modifying the definition of "BMT service" by removing the word stem as follows: "BMT service means the transplantation of proliferating hematopoietic ~~stem~~ cells essential to the survival of a patient derived from the bone marrow, the peripheral circulation, cord blood, or any other source."

Background:

The BMT standards were reviewed with a standard advisory committee (SAC) in 2015-2016 as well as an independent review. Draft language was presented to the CON Commission at its March 16, 2017 meeting, and the Commission chose to not adopt the language. The current effective date of the BMT standards is September 29, 2014.

The Department's rationale for deregulation is based on the following factors: The Centers for Medicare and Medicaid reimbursement offers stringent quality of care standards; this is a highly specialized service that has a high cost of maintenance, which prevents undue proliferation, the current CON standards do not regulate the service, there is only a cap in place, and only seven states currently regulate BMT service within a Certificate of Need program. In looking at nationwide access to BMT, Michigan's access is similar to states without Certificate of Need regulation.

BMT Survey Data for 2016:

Annual survey data for 2016 is the latest available and can be found here: http://www.michigan.gov/documents/mdhhs/Report_120-Organ_Transplant_Services_601022_7.pdf

Beaumont

January 31, 2018

VIA ELECTRONIC MAIL

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

Dear Commissioners:

On behalf of the citizens of Michigan, we strongly encourage you to assure that chimeric antigen receptor T-cell (CAR-T) therapy may be provided through all capable healthcare institutions in our state.

We are writing this letter in opposition to the recommendation proposed in October 2017 by Michigan Medicine and Karmanos Cancer Institute to include chimeric antigen receptor T-cell (CAR-T) therapy within the bone marrow transplantation (BMT) standards. There is no state in the U.S. regulating this therapy by Certificate of Need (CON). Although clinical trials are on-going for new targeted therapies, this method of treating cancer patients will become standard of care over the next decade.

CAR-T is one form of a new class of cancer therapies, referred to both as immune effector cell therapies (IEC) and as adoptive cell transfer therapies (ACT). They represent a distinctly different approach to existing therapies for cancer and are based on transforming a patient's own white blood cells to uniquely identify and eradicate their cancer.

CAR-T cell therapy does require that the treatment team and the treating institution have specialized expertise to care for very sick individuals. Like other complex medical procedures, CAR-T cell therapy and other cell therapies depend on research, clinical training, and adherence to quality standards developed by The Foundation for the Accreditation of Cellular Therapy (FACT), an independent, not-for-profit, internationally recognized accrediting body based in the U.S.

FACT released their First Edition for Immune Effector Cells Standards in January 2017, in advance of the FDA's approval (in August and October 2017) of the first two new CAR-T therapies. Their initial standards have been elucidated and supported in April in the *Journal for ImmunoTherapy of Cancer* 2017 5:36. FACT has further emphasized that immune effector cell standards (e.g., CAR-T) and hematopoietic cell therapy standards (e.g., BMT) have independent criteria.

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Regarding CAR-T, FACT states *"These standards are intended to be flexible to accommodate various models of patient care and use of cellular products. Requirements for programs that administer immune effector cells on a unit that is not FACT-accredited are contained fully in the FACT Immune Effector Standards".* **FACT does not require that a facility meet BMT accreditation to provide this level of care.**

The attached information below provides some additional detail on this new, evolving therapy and how care is organized in the interest of safety, quality for patients. While at an early stage of clinical development, these therapies and the several decades of research on which they're based hold substantial promise of providing cures for cancers not achieved through surgeries, chemotherapies, or radiation therapies.

We believe that CAR-T cell therapy should not be incorporated into the Commission's existing BMT Standard. By doing so, the CON Commission would be limiting access to important new therapies for patients across the state of Michigan.

Sincerely,

Malcolm S. Henoch, M.D., M.B.A.

Interim Chief, Beaumont Health Cancer Programs

SVP and Associate Chief Medical Officer, Beaumont Health

David P. Wood, M.D.

EVP and Chief Medical Officer, Beaumont Health

Carolyn Wilson, R.N., M.B.A.

EVP and Chief Operating Officer, Beaumont Health

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What is CAR-T Cell Therapy?

CAR T-cell therapy begins by collecting a patient's white blood cells (T-cells) and sending them to a central manufacturing facility where they are genetically modified to direct them against a patient's cancer. Once processed, the CAR T-cells are frozen and sent back to the hospital for IV infusion back into the patient.

Before the patients receives their CAR T-cells, they undergo a short chemotherapy regimen to condition their body to receive the cells. Once infused, the CAR T-cells proliferate inside the body, and begin to recognize and attack cancer cells.

From the patient treatment perspective, the process is as follows[1]:

1) Patient is diagnosed with qualifying condition and is referred to treatment center.
2) Patient travels to treatment center for initial consultation and treatment planning; returns home or remains at treatment center for on-going treatment of disease.
3) Patient travels to treatment center to have cells removed through a process called autologous apheresis or leukapheresis; this may be conducted in either the ***inpatient or outpatient*** setting.
4) The hospital places order for production and ships patient cells to manufacturer; patient likely returns home for 2-3 weeks during the CAR-T production process.
5) Up until for infusion of CAR-T product, the patient will likely be receiving chemotherapy to control disease progression. This may be administered inpatient or outpatient.
6) Patient travels to treatment center for infusion of the CAR-T product after being notified of successful manufacturing and estimated arrival date.
7) ***Patient is admitted for preparatory lymphodepleting chemotherapy and CAR-T infusion.*** *The patient remains in the hospital for 7-10+ days, depending on the patient's individual response and until the treating physician team feels confident that the patient is not experiencing moderate to severe complications. Outpatient provision of CAR-T will likely be available in limited sites for specific patients but will not be common during the initial post-approval period.*
8) For approximately 15-30% of patients of patients, moderate to severe complications will result in staying in the hospital for up to 3 weeks as symptoms are being treated. Cytokine Release Syndrome (CRS) symptoms will begin appearing in affected individuals within 2-7 days after infusion with the product and neurotoxicity typically appears within 5-7 days of infusion.
9) Patient remains nearby the treatment center for an additional 1-2 weeks for monitoring.
10) Patient returns home for on-going monitoring with local clinical teams.

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CARTOX Working Group Recommendations for Supportive-care considerations for CAR-T-cell therapy[2,3]

Before and during CAR-T-cell infusion:

- Baseline brain MRI to rule out any central nervous system (CNS) disease
- Central venous access, preferably with double or triple lumen catheter, for intravenous fluid and other infusions in case of toxicities
- Cardiac monitoring by telemetry starting on the day of CAR-T-cell infusion and continued until CRS resolves, in order to detect arrhythmias
- Tumour lysis precautions for patients with bulky tumours, as per standard institutional guidelines
- Seizure prophylaxis with levetiracetam at 750 mg orally every 12 hours for 30 days, starting on the day of infusion for CAR-T-cell therapies known to cause CRES
- Hospitalization recommended for at least 7 days after CAR-T-cell therapy

Patient monitoring after CAR-T-cell infusion:

- Assess vital signs every 4 h, close monitoring of oral and intravenous fluid input and urine output, and daily measurement of bodyweight
- Daily review of patient history and physical examination
- Daily blood counts, complete metabolic profiling, and coagulation profiling
- C-reactive protein and ferritin levels measured daily, starting on the day of infusion
- Assessment and grading of CRS should be done at least twice daily, and whenever the patient's status changes
- Assessment and grading of CRES using the CAR-T-cell-therapy-associated toxicity 10-point neurological assessment (CARTOX-10) should be done at least every 8 hours
- Maintenance intravenous fluids with normal saline to ensure adequate hydration

Notifications and contingency orders:

- The physician should be notified on detection of any of the following: systolic blood pressure (SBP) >140 mmHg or <90 mmHg; heart rate >120 bpm or <60 bpm, or arrhythmia; respiratory rate >25 breaths per min or <12 breaths per min; arterial oxygen saturation <92% on room air; urine output <1,500 ml per day; upward trend in blood creatinine levels or the results of liver function tests; tremors or jerky movements in extremities; change in mental status (alertness, orientation, speech, ability to write a sentence, or CARTOX-10 score)
- For patients with a temperature ≥38.3 °C, order blood cultures (central and peripheral), urinalysis and urine cultures, portable chest radiography, and notify physician

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- For patients with neutropenia and fever, start empiric broad-spectrum antibiotics
- Corticosteroids should not be administered unless approved by physician
- If patient develops CRES, withhold oral intake of food, fluids, and medicine, and notify physician
- *Pro re nata* (as needed) medications, acetaminophen (first choice) or ibuprofen (second choice, if not contraindicated), and cooling blanket for fever ≥38.3 °C; normal saline 500–1,000 ml bolus for SBP <90 mmHg, with one repeat if SBP remains <90 mmHg after first bolus
- Anti-IL-6 therapy with tocilizumab or siltuximab to be initiated only on physician order

References:

1. Komanduri, Kkrishna, MD. Re.CMS Payment Models for Chimeric Antigen Receptor T Cell (CAR-T) Therapy. American Society for Blood and Marrow Transplantation. September 6, 2017
2. http://www.esmo.org/Oncology-News/Assessment-Grading-and-Management-of-Acute-Toxicities-From-CAR-T-Cell-Therapy, Accessed 14 January 2018
3. Neelapu S, Tummala S, Kebriaei P, *et al.* Chimeric antigen receptor T-cell therapy — assessment and management of toxicities. Nature Reviews Clinical Oncology; Published online 19 Sep 2017
4. FACT – Foundation for the Accreditation of Cellular Therapy at the University of Nebraska Medical Center. Standard for Immune Effector Cells. First Edition. January 2017.
5. Marcela V. Maus and Sarah Nikiforow, The why, what, and how of the new FACT standards for immune effector cells. *Journal for ImmunoTherapy of Cancer*20175:36 https://doi.org/10.1186/s40425-017-0239-0
6. Introducing the FACT standards for Immune Effector Cells. http://www.factwebsite.org/uploadedFiles/Educational_Opportunities/Immune%20Effector%20Cell%20Standards.pdf

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MDHHS Recommendations for CON Standards Scheduled for 2018 Review

Heart/Lung and Liver Transplantation (HLLT) Services Standards			
Department Recommendations: The Department continues to urge the Commission to either deregulate or develop a needs-based methodology for this service.			
Identified Issues	**Issue Recommended for Substantive Review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Other technical edits by the Department if needed.			None identified.

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "…review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the HLLT Services Standards are scheduled for review in calendar year 2018.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 6 - 20, 2017. Testimony was received from four (4) organizations and is summarized as follows:

1. *Dennis McCafferty, The Economic Alliance for Michigan (EAM)*
    - EAM member organizations are not convinced that allowing additional HLLT programs in Michigan would result in improved access, increased utilization, lowering the cost or improving the quality of these services for the citizens of Michigan.
2. *T. Anthony Denton, University of Michigan Medicine*
    - Supports continued regulation of HLLT services and recommends no changes at this time.

3. *Marwan Abouljoud, MD, Henry Ford Health System (HFHS)*
    - Supports continued regulation of HLLT services and recommends no changes at this time.

4. *Patrick O'Donovan, Beaumont*
    - Supports continued regulation of HLLT services and recommends no changes at this time.

Background:

The HLLT standards were most recently reviewed with a standard advisory committee (SAC) in 2009. The current effective date of the HLLT standards is September 28, 2012.

The Department has recommended deregulation of this service when the CON Commission last reviewed this service in 2015 and 2012. When the service was reviewed in 2009, the Department recommended removing the "cap" on the service.

The Department's rationale for recommended deregulation is based on the following factors: this service has a very low number of cases and has external state and national bodies that monitor quality and costs. For example, programs must already comply with the federal Center for Medicare and Medicaid Services (CMS) quality and volume requirements and adhere to United Network for Organ Sharing (UNOS) and Organ Procurement and Transplantation Network (OPTN) certification.

HLLT Survey Data for 2016:

Annual survey data for 2016 is the latest available and can be found here: http://www.michigan.gov/documents/mdhhs/Report_120-Organ_Transplant_Services_601022_7.pdf

MDHHS Recommendations for CON Standards Scheduled for 2018 Review

Magnetic Resonance Imaging (MRI) Services Standards

Department Recommendations: MRI services/units should continue to be regulated by CON. There are no recommended changes at this time. The next review will be in 2021.

Identified Issues	Issue Recommended for Substantive Review?	Recommended Course of Action to Review Issues	Other/Comments
Section 4(1) financial cap for equipment changes: HFHS recommends that the definition of 'Replace an existing MRI unit' be modified and updated to remove the capital expenditure threshold for an equipment change that does not require CON approval.	No.		Department Comment: There would not be any way to administer this language as MRI equipment would not be registered with any other state entity (i.e. Radiation Safety).
Section 5(1)(b) volumes for expansion: HFHS recommends the minimum volume requirement of 11,000 adjusted procedures per unit be reduced to 10,000.	No.		Department Comment: This issue was reviewed in the 2015 workgroup and no changes were made.
Section 15(1)(a) weighting: HFHS recommends that procedures requiring general anesthesia be considered for an increase in weighting with a base value weight of 2.0.	No.		Department Comment: There is already an additional weight provided in the CON standard for sedated patients (1.75) and extra for a re-sedated patient (0.25).
Section 18· Physician Pledge forms: HFHS recommends there be a formal Q&A document included with physician pledge forms, clearly outlining what pledging volumes means for a physician when signing a pledge form.	No.		Department Comment: This is not a standard change. Forms CON-220 and CON-220-A provide instructions and explanations.
UMHS recommends a workgroup to review a definitional change regarding pediatric patients by increasing the age limit for pediatric MRI	No.		Department Comment: Changing the definition of child/adolescent would have implications for other CON standards. Current CON standards

studies through 21 years of age (<22 years of age).			do not prohibit patients aged 18-21 from receiving treatment on dedicated pediatric MRI unit as long as 80 percent of the procedures on the dedicated unit are done on patients less than 18 years of age.
Other technical edits by the Department if needed.			None currently identified.

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "…review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the MRI Services Standards are scheduled for review in calendar year 2018.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 6 - 20, 2016. Testimony was received from six (6) organizations and is summarized as follows:

1. *Sean Gehle, Ascension Michigan*
    - Supports continued regulation of MRI services and recommends no changes at this time.

2. *Dennis McCafferty, The Economic Alliance for Michigan (EAM)*
    - Supports continued regulation of MRI services.

3. *Patrick O'Donovan, Beaumont*
    - Supports continued regulation of MRI services and recommends no changes at this time

4. *Cheryl Martin, Henry Ford Health System (HFHS)*
    - Supports continued regulation of MRI services with the following recommendations:
        - "Section 4(1) financial cap for equipment changes: HFHS recommends that the definition of 'Replace an existing MRI unit' be modified and updated to remove the capital expenditure threshold for an equipment change that does not require CON approval. The current threshold is outdated and we believe it would be simpler and more clear to allow for any equipment changes and/or upgrade to a MRI machine that does not lead to a change in the machine's serial number without CON approval. This is consistent with similar provisions in the CT standards."
        - "Section 5(b) volumes for expansion: HFHS recommends the minimum volume requirement of 11,000 adjusted procedures per unit

be reduced. HFHS MRI services are operational 16 hours a day, 7 days a week at some of our facilities, and patient services are being delayed due to lack of availability of machines. Even with this extended service times, we struggle to meet the 11,000 requirement for expansion at these sites. HFHS recommends the minimum adjusted procedure requirement be reduced to 10,000."

- "Section 15(1) (a) weighting: HFHS recommends that procedures requiring general Anesthesia be considered for an increase in weighting. The current weighting does not take into consideration the extended period of time the patient is in the MRI during pre and post procedure care due to the Anesthesia requirements. HFHS recommends adding procedures under general anesthesia to (a) with a base value weight of 2.0."
- "Section 18 Physician Pledge forms: HFHS recommends there be a formal Q&A document included with physician pledge forms, clearly outlining what pledging volumes means for a physician when signing a pledge form. We have seen slightly misleading Q&A documents distributed to HFHS physicians in the past. A standard Q&A would help physicians understand what commitment of volumes means to them and their patients, and protect both the physician and institutions involved in the process."

5. *T. Anthony Denton, et al, University of Michigan Medicine*
   - Supports continued regulation of MRI services and recommends the following change:
     - UMHS recommends a workgroup to review a definitional change regarding pediatric patients. "UMHS recommends increasing the age limit for pediatric MRI studies through 21 years of age (<22 years of age). This change is necessary to reflect the practice of pediatric medicine in the current era. This change is critical to assure proper health care for the entire 'pediatric' patient population."

6. *Robert Casalou, Saint Joseph Mercy Health System*
   - Supports continued regulation of MRI services and recommends no changes at this time.

Background:

The MRI standards were reviewed with a workgroup in 2015. The current effective date of the MRI standards is October 21, 2016.

MRI Survey Data for 2016:

The MRI Utilization List data for November 1, 2017 is the latest available and can be found here: http://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5106-116465--,00.html

MDHHS Recommendations for CON Standards Scheduled for 2018 Review

Psychiatric Beds and Services Standards			
Department Recommendations: Psychiatric Beds and Services should continue to be regulated by CON. The Commission should form a standard advisory committee (SAC) to make a recommendation regarding the issues outlined below.			
Identified Issues	**Issue Recommended for Substantive Review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Add Nurse Practitioners and Physician Assistants to definition section individually and include as part of "Mental Health Professional" in the Project Delivery Requirements.	Yes.	Form a Standard Advisory Committee	Department Comment: This definition should be reviewed completely to determine if other updates are necessary and to determine the impact throughout the standard.
Determine if "developmentally disabled," "geriatric Psych," and "medical Psych" need to be called out separately in the definitions section (2)(j) "Department inventory of beds."	No.		Department Comment: These types of special pool beds are separate from the regular inventory of beds, and they are defined in the addendum.
Explore options for flexibility to transfer beds and/or create units with existing child/adolescent and adult beds.	Yes.	Form a Standard Advisory Committee	
Review the methodology for determining the inpatient psychiatric bed need in the state, including the proper percentage of psychiatric beds that should be allocated to the special pool for psychiatric beds.	Yes.	Form a Standard Advisory Committee	Department Comment: The Department supports and also recommends reviewing the methodology.
Review Section 14(3)(b)(i) access to care: the current language in (3)(b)(i) does not call out that access may be denied if the admission creates an unsafe environment for the patient and/or staff. Clarify when denial of access is permissible.	No.		Department Comment: Current CON standards state that each provider "*must assure appropriate utilization for all segments of Michigan's population and cannot deny service to any individual based on ability to pay, source of payment, age, race,*

			handicap, national origin, religion, gender, sexual orientation or commitment status." Further, the CON standards state that "*the provider shall establish procedures to care for patients who are disruptive, combative, or suicidal and for those awaiting commitment hearings*." Patient and staff safety is of critical importance, and the current standards require Psychiatric Inpatient providers to establish procedures to ensure access to care along with staff and patient safety.
Review the comparative review criteria.	Yes.	Form a Standard Advisory Committee	
Review criteria for the special pool beds.	Yes.	Form a Standard Advisory Committee	
Allow the MDHHS staff to move unallocated beds from the different special population bed categories as they deem appropriate.	No.		Department Comment: Allocating special population beds can be addressed as part of the methodology already noted.
Add clarifying language, as appropriate, in each subsection of Section 9 to assist in understanding which subsection(s) apply under what circumstances (e.g., adding new beds from dept. inventory, adding new beds under high occupancy, relocate beds, etc.)	Yes.	Department will draft language.	This issue was identified by the MDHHS CON Evaluation section.
Add minimum occupancy requirements in last 12-month prior to application submission, as in hospital beds standards, for the existing psych hospital/unit before a new entity	Yes.	Form a Standard Advisory Committee	This issue was identified by the MDHHS CON Evaluation section.

can acquire the facility, replace the facility, or relocate beds.			
Other technical edits by the Department if needed.		Department will draft language.	

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "…review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the Psychiatric Beds and Services Standards are scheduled for review in calendar year 2018.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 6 - 20, 2017. Testimony was received from nine (9) organizations and is summarized as follows:

1. *Sean Gehle, Ascension Michigan*
    - Add Nurse Practitioners and Physician Assistants to definition section individually and include as part of "Mental Health Professional" and in Project Delivery Requirements.
    - Determine if "developmentally disabled," "geriatric Psych," and "medical Psych" need to be called out separately in the definitions section (2)(j) "Department inventory of beds."

2. *Dennis McCafferty, The Economic Alliance for Michigan (EAM)*
    - Supports identifying other potential solutions to Michigan's patient's ability to access psychiatric beds and services.

3. *T. Anthony Denton, University of Michigan Medicine*
    - Supports continued regulation of Psychiatric Beds and services and recommends no changes at this time.

4. *Patrick O'Donovan, Beaumont*
    - "Look for solutions and approaches to better serve behavioral health patients, there should be flexibility to serve both adult and child/adolescent patients. Beaumont Health requests that the Commission support this flexibility and explore ways to accomplish this. One option could be to allow adult psychiatric units with a certain number (TBD) of beds to be allowed to establish a child/adolescent unit with a smaller number (TBD) of child/adolescent beds. An alternative option would be to allow a some (but not necessarily all) child/adolescent beds to be transferred from one child/adolescent psychiatric unit to a facility that currently has an adult psychiatric unit (thus creating a new child/adolescent psychiatric unit but no increase in child/adolescent beds)."

5. *Robert Casalou, Saint Joseph Mercy Health System*
    - Supports continued regulation of Psychiatric Beds and Services and recommends no changes at this time.

6. *Eric Fischer, Detroit Medical Center (DMC)*
    - The DMC supports the overall regulations for this service; however, they "would like the CON Commission to review the methodology for determining the inpatient psychiatric bed need in the state, including the proper percentage of psychiatric beds that should be allocated to the special pool for psychiatric beds."

7. *Dr. Cathy Frank, Henry Ford Health System (HFHS)*
    - HFHS supports continued regulation of Psychiatric Beds and Services. However, they would like the CON Commission to review Section 14(3) access to care: They are recommending slight revisions to the language in (3)(b)(i). They believe the intent of sections (2)(b) and (3)(b)(i) is to guarantee access to an inpatient environment that allow for safe, high quality care. However, the current language in (3)(b)(i) does not call out that access may be denied if the admission creates an unsafe environment for the patient and/or staff. Specifically, given the organization of patient pods in a facility (male vs. female, adult vs. child/adolescent) access may be denied based on gender or age if that admission creates an unsafe environment. HFHS is requesting language be added to this section to clarify when denial of access is permissible.

8. *Bob Nykamp, Pine Rest Christian Mental Health Services*
    - Pine Rest is requesting that clinical quality comparative review requirements be added to the standards.
    - Pine Rest is asking "the commission to allow the staff to move un allocated beds from the different special population bed categories as they deem appropriate."

9. *Gwen Sandefur, Spectrum Health*
    - Spectrum Health would like the CON Commission to consider allocating additional beds to the special pools, specifically the geriatric and medical psych pools.
    - Spectrum Health would like the Department to contract with Dr. Paul Delamater to review the methodology and recommend replacement or modification.

Background:

The Psychiatric Beds and Services standards were reviewed with a workgroup in 2015. The current effective date of the Psychiatric Beds and Services standards is December 9, 2016.

Psychiatric Beds and Services Survey Data for 2016:

Annual survey data for 2016 is the latest available and can be found here: http://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5106-312854--,00.html

Megavoltage Radiation Therapy - Certificate of Need Standards Review: HMRT or Proton Therapy

Reshma Jagsi, MD, DPhil
Professor and Deputy Chair, Department of Radiation Oncology
Director, Center for Bioethics and Social Sciences in Medicine
University of Michigan

Overview

- Radiotherapy is a critical component of the multimodal management of cancer
- Both oversupply and undersupply are suboptimal for society
  - Undersupply creates access issues
  - Oversupply can waste resources
- The Commission is critical in protecting the citizens of our State from these risks
  - Must ensure standards are current and reflect modern circumstances, including:
    - Responsiveness to demonstrated patient need
      - Acknowledgement of rising incidence of cancer
      - Embrace of emerging evidence supporting broader clinical indications for proton therapy
    - Lower cost of proton therapy centers compared to 10 years ago
    - Reorganization and consolidation of care in the State

Michigan Citizens Deserve Reasonable Access to Proton Therapy

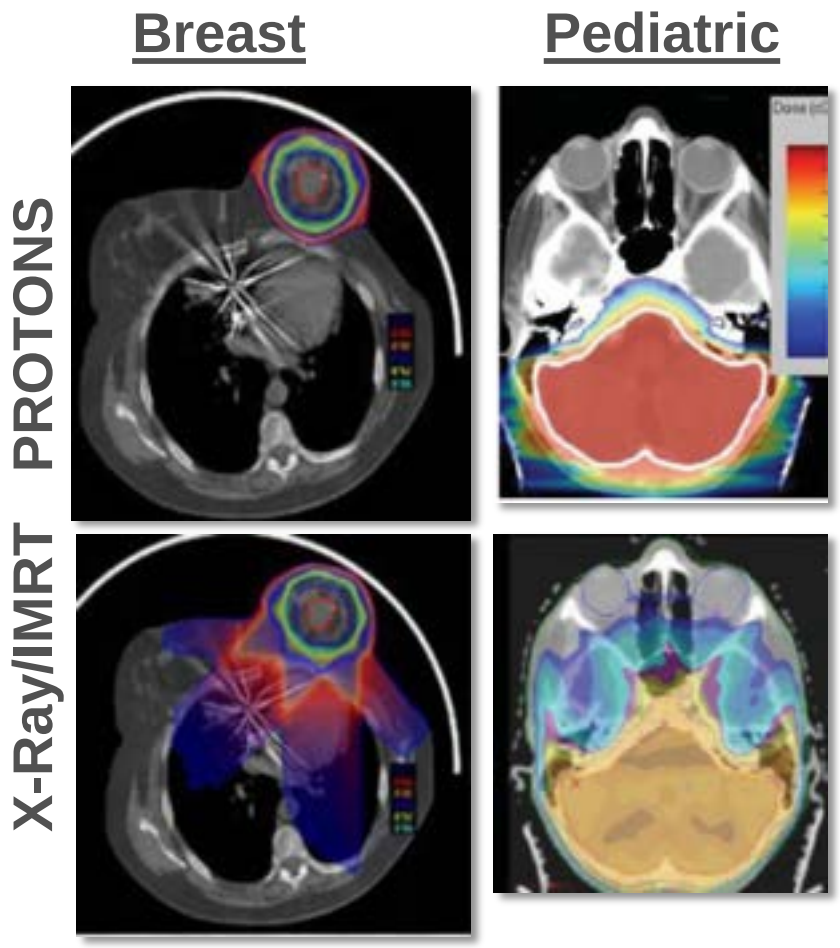
Attachment F

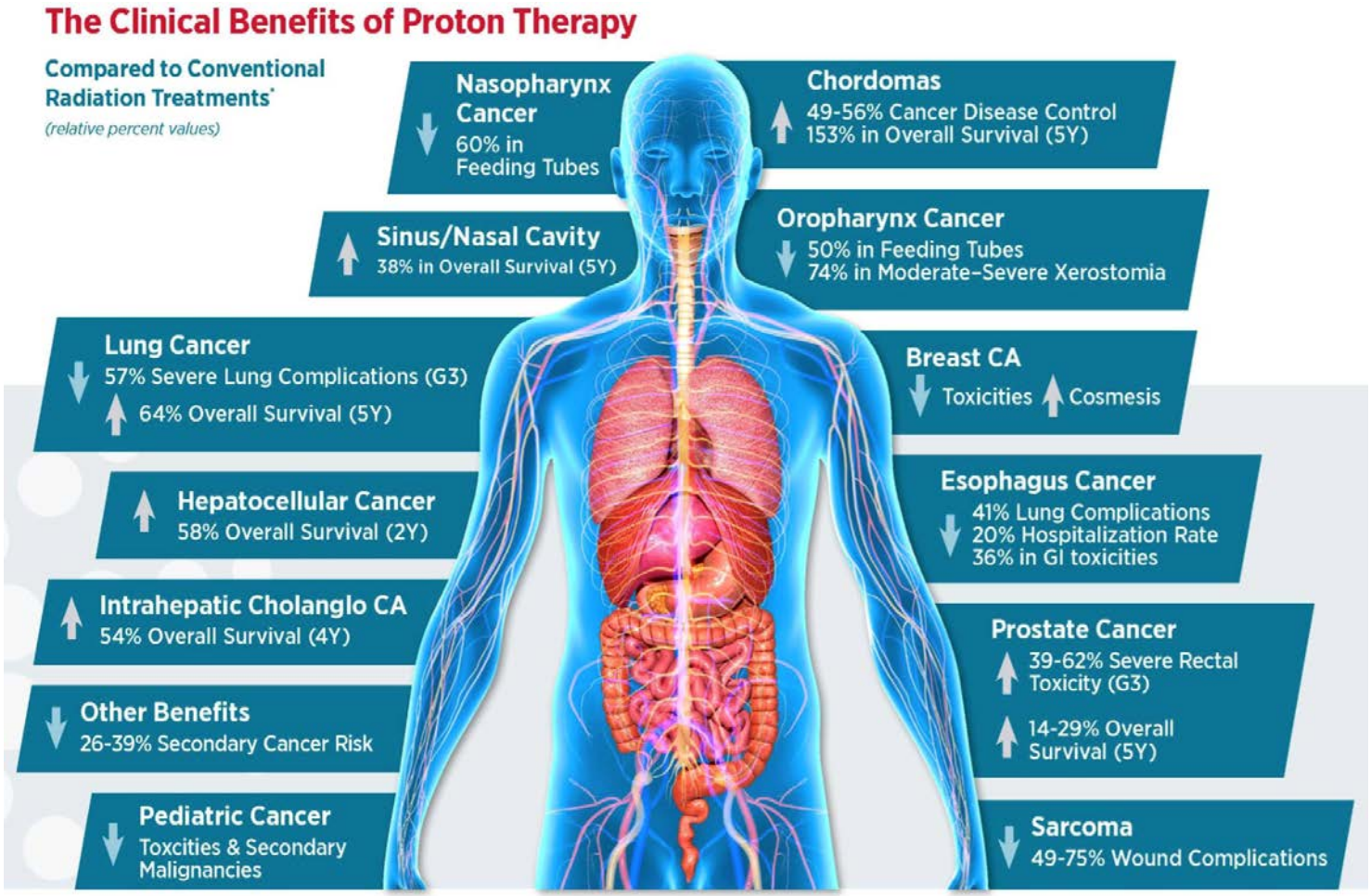
- Proton Therapy is a powerful cancer-fighting tool that targets tumors more effectively and significantly lowers radiation dose to healthy tissue
- Children treated for cure most likely to benefit
  - Lower risks of second cancers, growth delays, impaired cognition, and other damage that lasts a lifetime
  - UM Mott Children's Hospital cares for most pediatric cancer patients in Michigan, leveraging resources of the University's Comprehensive Cancer Center to offer complete care in a patient-centric manner
  - Forcing families to travel for children to receive radiation in an environment less specialized in pediatric cancer care creates a fragmented and suboptimal care experience

Evidence Accumulating to Support Broadening Indications

Attachment 5

Protons deliver 1/3 to 2/3 LESS dose to healthy tissue than X-rays: evidence for clinical benefits emerging for adult as well as pediatric patients





Current Clinical Need in Michigan: Substantial

- Thousands of patients in the State of Michigan each year could benefit from proton therapy
  - Given 336 pediatric and 50,839 adult incident cancers in 2015, Advisory Board estimates that **63 pediatric (19%) and 7964 adult patients (16%)** could benefit from proton therapy, including:
    - 232/644 (36%) adults with brain/nervous system cancer
    - 798/2451 (33%) adults with head and neck cancer
    - Many others with sarcomas, liver tumors, and more
  - Note: Does not include potential cases requiring re-treatment
  - **Half live within 50 miles of UM**
  - And all projections show cancer incidence is rising

Redefining Need: How the Times Have Changed

- Ten years ago:
  - Radiotherapy was provided by more and smaller facilities
  - Only 5 providers had >30,000 ETVs
  - 2/5 were required (40%) to have qualifying activity and form a collaborative

- Now:
  - Due to consolidation, 6 providers have >30,000 ETVs, so a new entrant needs a 3rd partner to exceed 40%
  - 2 of these 6 providers already have facilities (only one functioning)
    - Existing facilities are far smaller than anticipated when policy was written and can treat only a small fraction of proton-eligible cases in the state
    - Based on guidance from MDHHS, these 2 providers must remain in the calculation of eligible services with >30,000 ETVs

Redefining Need: Activity Should Be the Key Consideration

- UM has **double** the activity threshold on its own, with >60,000 ETVs at its main medical campus
- UM has a willing partner with whom to collaborate, with activity >30,000 ETVs within the same Health Service Area (HSA)
- UM has an emerging system of radiotherapy in other geographic HSAs, with expanding cancer program presence and therapeutic demand
- The 40% rule is an unreasonable “third qualifier”, creating a barrier to access required cancer care services in an integrated and cost-efficient manner

Current Facilities Cannot Meet Clinical Need

- Thousands of Michigan patients could benefit from additional capacity, but existing facilities cannot meet present and future needs
  - Beaumont has the only active facility in Michigan
- This year, over 50 of our patients were referred elsewhere to receive proton therapy
  - Typically cases are sent to other comprehensive cancer centers (MD Anderson, MGH)
  - Many others lack the resources to travel to receive the best care
- Access in the State of Michigan to proton therapy is inadequate, requiring a review of the present CON requirements

Costs and Scale of Proton Therapy Dramatically Lower Now

- Cost containment was a primary driver of the development of the current CoN Standards

- 2009 article describes $144M center being constructed at the University of Pennsylvania as “the most complex and expensive medical machinery ever built”

- 2015 Wall Street Journal article focused on compact proton systems costing $25-$30M, a dramatic revolution in cost and scale

Must Serve Citizens' Needs: Today and Tomorrow

- Beyond serving the patients who benefit from proton therapy today, UM uniquely positioned within the State to ensure that even more patients benefit tomorrow
  - UM has a top 5 radiation oncology department in the country
    - Has the expertise needed to lead the research needed to make proton therapy even more useful
    - Many resources, including a $15M program project grant from the National Cancer Institute, can be leveraged to help citizens in our state and beyond
    - Optimally positioned to lead the studies needed to improve the use of protons and optimize resource utilization

Summary: A CON Standards Review is Recommended

Attachment F

- Per existing standards, UM qualifies based on activity and collaboration
- Activity is basis for qualification in most CON Standards
- No applicants for Proton Centers since the current language was written: a sign that the current standards discount patient activity as a key “need” criteria
- Project costs have been reduced significantly over time
- We recommend a Standards Advisory Committee or Workgroup to review the existing HMRT standards and clarify “need” criteria to qualify for a proton facility and improve reasonable access to care for Michigan citizens

Beaumont

Beaumont Proton Therapy Center

Craig W. Stevens, M.D., Ph.D.
Professor and Chair
Department of Radiation Oncology
Beaumont Health

February 8, 2018

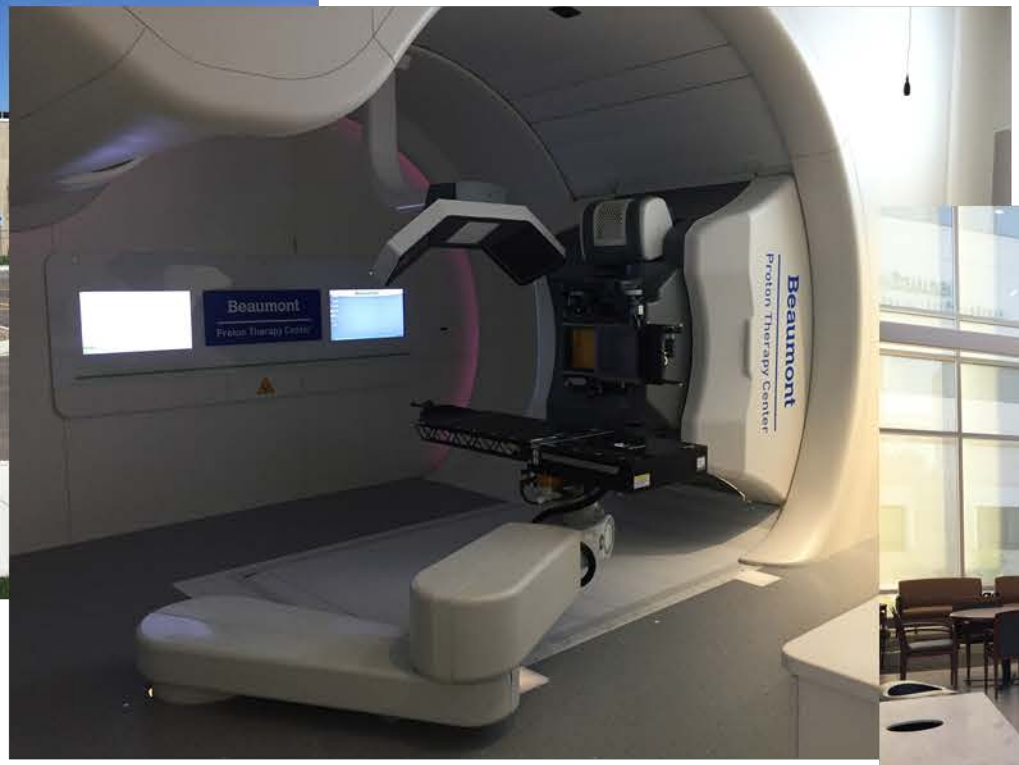
Introduction

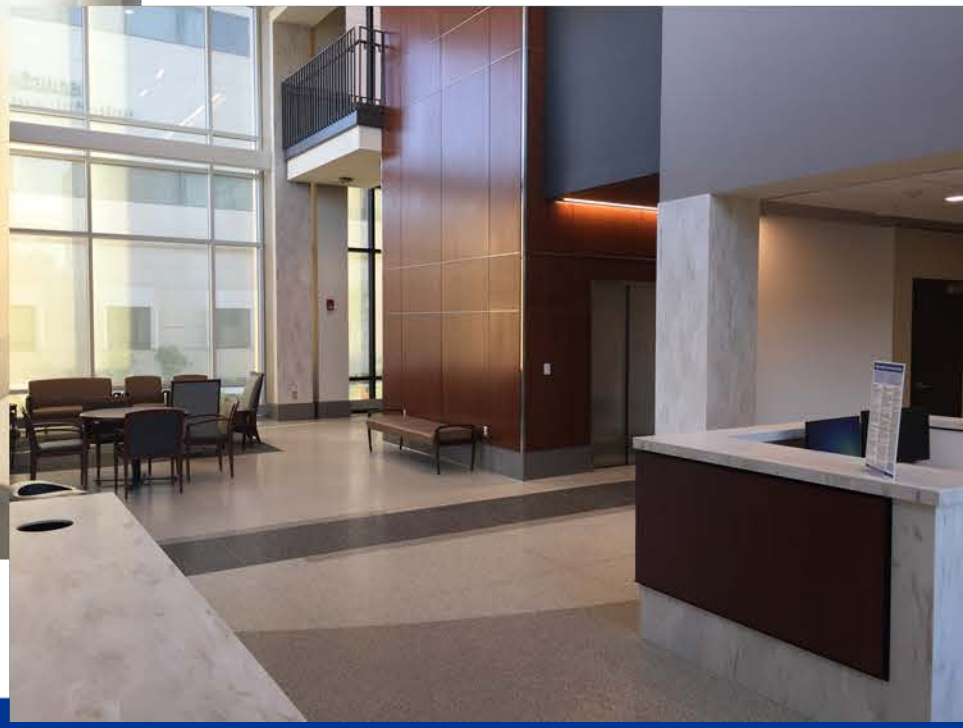
- Beaumont safely and successfully installed, commissioned the first proton center in MI to serve needs across the state
- This allowed us to
  - Treat the first proton patient in MI
  - Treat the first pediatric patient with protons in MI
  - Develop new knowledge through study and clinical research to optimize the current and future application of this new modality for cancer

Beaumont Health Radiation Oncology

- Radiation Oncology has a long history of academic success and innovation
  - Cone Beam CT
  - Active Breathing Control
  - Adaptive Oncology
- Funding
  - NIH Grants $16.3M in direct costs (+51% indirects)
  - Congress mandated $2.2M
  - Miscellaneous $13.4M in direct costs (+15%-33%)
  - Beaumont research $3.3M
  - IP $2.5-$3.5M per year
- Publications
  - Annual publication >50/year

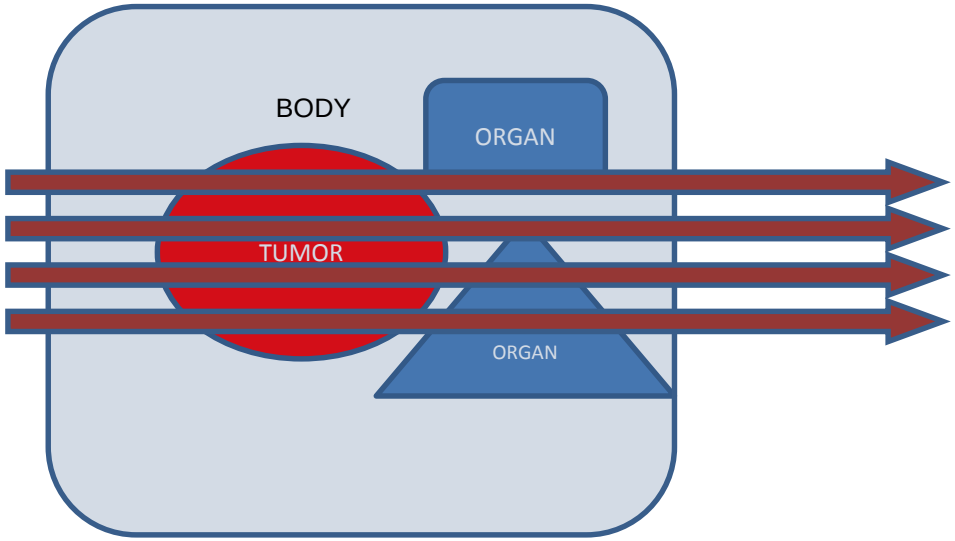
Beaumont Proton Therapy Center



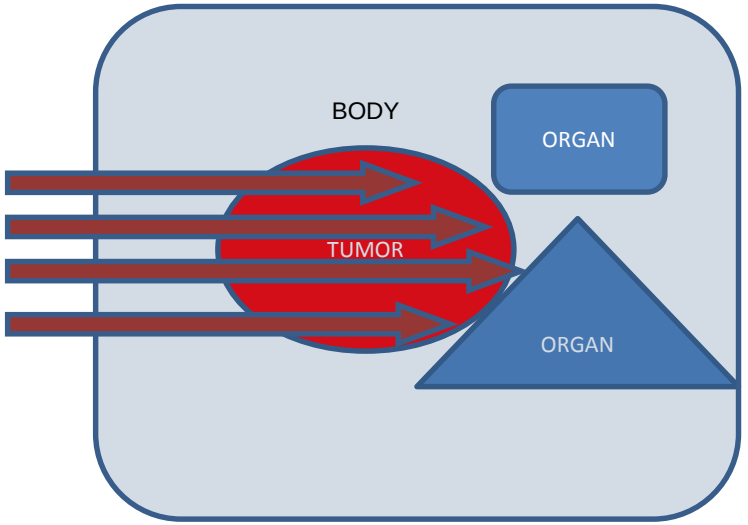


Physics of Proton Therapy

- Photons



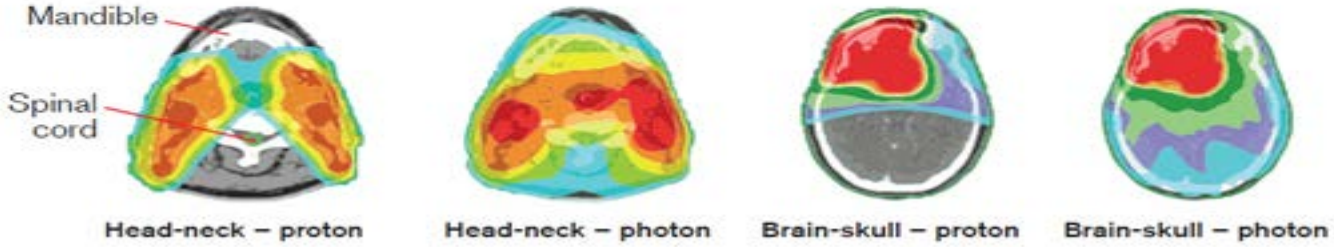
- Protons

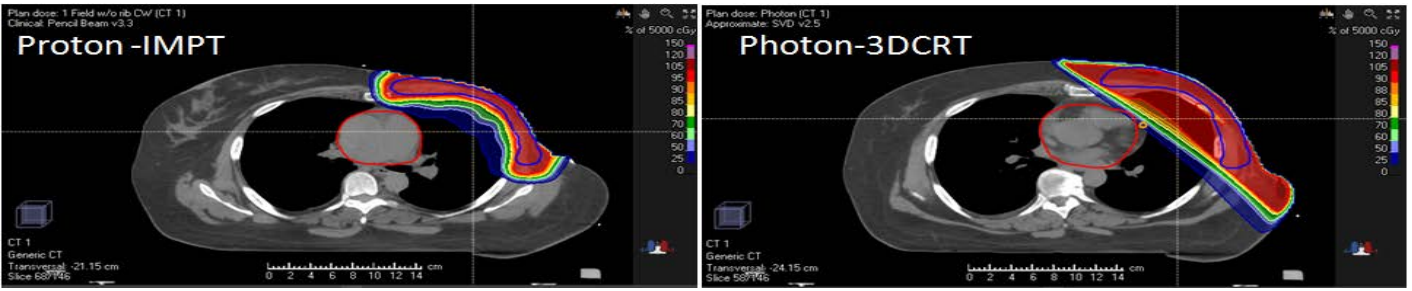


Treatment Comparisons

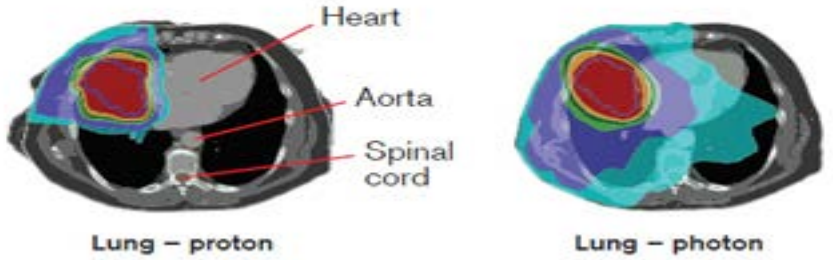
Protons vs IMRT photons: less dose to healthy tissue

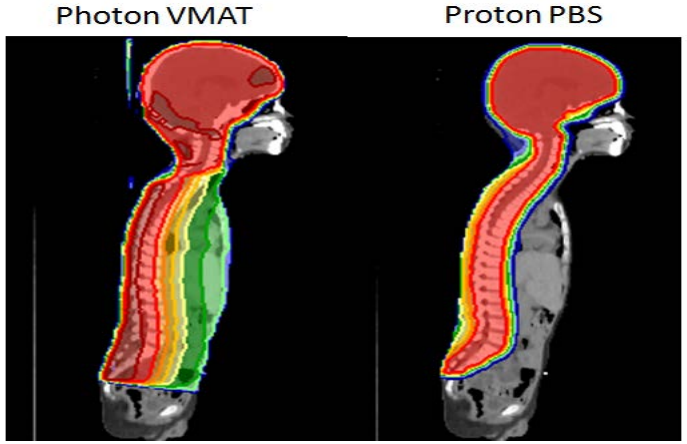
Head, Neck and Brain





Lung





Beaumont Proton Therapy Center

- Our center has pencil beam scanning and 3 options for daily imaging
  - PBS = Very precise delivery of dose to tumor
  - In-room imaging = Very precise patient/tumor setup
  - This further reduces normal tissue doses
  - Better dose to tumor with less side effects!!!
- Skandalaris Family Center for Children with Cancer and Blood Disorders relocated to second floor of Proton Therapy Center
  - Most vulnerable population is within the same facility (Patient-centered)

Beaumont Proton Therapy Center Expertise

- Fellowship trained radiation oncologists in proton therapy
  - Harvard Medical School
  - University of Florida Proton Therapy Center
  - MD Anderson
- Medical physicists were trained and recruited from other proton therapy centers
- Dedicated training for all staff at two proton therapy centers before go-live
- ***There is a limited talent pool for experienced staff in proton therapy***

Proton Therapy Commissioning

- Proton commissioning is not like a linear accelerator
  - Each disease site is commissioned separately and requires
    - Robust immobilization
    - Confirmation of CT characteristics for that site
    - Development of an imaging plan
    - Development of adaptive planning strategy
    - Multiple dry runs
    - Separate plan for pediatrics
  - Some require
    - Anesthesia
  - Beaumont is still in the process of commissioning mobile tumors

Beaumont

Proton Center 1st Patient Treatment
June 28, 2017

Proton Therapy Centers

http://www.proton-therapy.org/map.htm

- 26 operational centers in U.S.
- 11 under construction
- Beaumont still has capacity to accept patients
- McLaren Flint proton center is scheduled to open in 2018
- There is enough capacity in Michigan to manage those patients needing this treatment

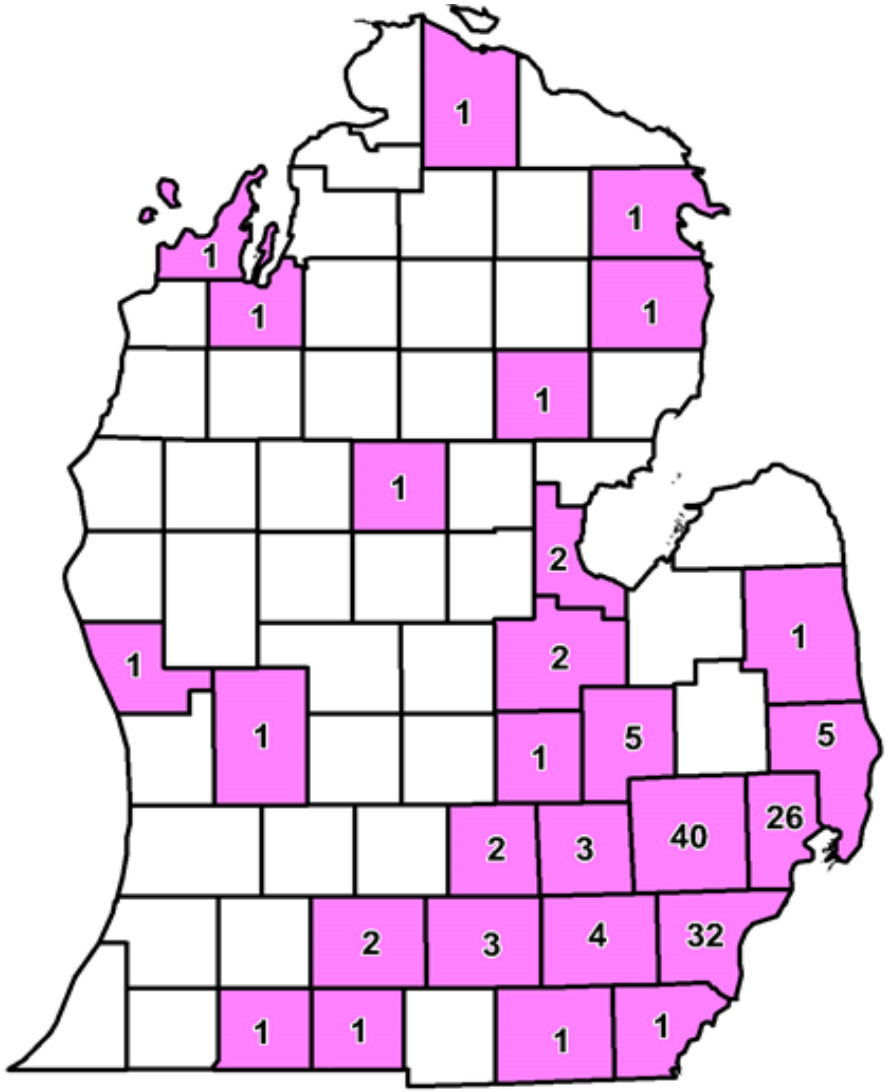
Proton Therapy Center Knowledge Sharing Events

- Tours and open houses invitees:
  - Michigan Department of Health and Human Services (MDHHS) CON section
  - MDHHS senior staff including Nick Lyon
  - Invited over >100 physicians to an open house
- Formal presentations were given for pediatric cancer patients
  - University of Michigan
  - Spectrum Health
- Invited CON commissioners to tour the proton center
- All welcome with advance notice (to avoid patient disruption)

We are serving our community across Michigan

- Our first patient treated is from Saginaw
- Patients are coming from Muskegon to Leelanau to Algonac to Monroe
- We are also assisting patients from Illinois, Indiana, and Ohio
  - Utilizing telehealth to assist with patient screening
- We believe this is an asset that serves all the citizens of the state of Michigan and the Great Lakes region

Proton Patient Consults Across the State and Beyond



Other patients consults:	
California	2
Florida	2
Georgia	1
Illinois	2
Indiana	2
Louisiana	1
Ohio	2
Tennessee	2
Texas	1
Wisconsin	1
Canada	4
Dubai	1

Proton Therapy Center Productivity

- 47 patients treated
  - 10 children (2 with anesthesia)
- Last 2 months census
  - 12 – 20 (center max 30 – 35 depending on complexity)
- Patient referrals
  - University of Michigan Mott Hospital
  - Children's Hospital
  - Henry Ford Health System
  - Ascension Health System
  - Spectrum Health

Proton Therapy Center Access

- Developed convenient/efficient access process for patients & physicians offices
- Minimize handoffs to provide a seamless experience for the patient
  - Developed a nurse navigator process to assist with patient intake and coordination of care
- The patient should always leave with a next step appointment scheduled and/or a treatment plan
- No patients will be treated without pre-authorization
  - Reduce financial burden to patient and family

Proton Therapy Chart Rounds

- Every patient that is recommended for proton therapy is reviewed at a dedicated chart rounds
- The clinical team includes physicians, medical physics, nursing, radiation therapy and administration
- If a patient does not proceed for proton therapy based on guidelines, they are presented with other treatment options
- In addition, Beaumont developed a Proton Therapy Ethics committee to determine appropriate patient selection

Proton Therapy Ethics Committee

- Ethics committee was formed to help with triaging the appropriate patients for new therapy
- Guidance on the development of a transparent ethical structure for patient triage once the machine is full.
  - U Penn has developed a point system (accounts for diagnosis, site, stage, PS, age, urgency, clinical protocol) that will be modified to fit our system.

During this time we also….

- Dr. Ding has developed a process for rotational IMPT with PBS
- Developed a sponsored research program with IBA
- Submitted R03 for technology development
- Published and presented extensively on proton therapy
- Enhanced authorization and billing process
  - Only one patient ultimately failed authorization

Summary

- Beaumont successfully installed and commissioned the first proton center in MI
- This allowed us to
  - Treat the first proton patient in MI
  - Treat the first pediatric patient with protons in MI
  - Develop novel intellectual property that will improve the future of proton therapy
- We care and serve patients across MI while returning them to their referring team
- Beaumont welcomes the CON Commissioners to visit our center

Questions?

Attachment H

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) PROGRAM

ANNUAL ACTIVITY REPORT

October 2016 through September 2017
(FY2017)

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

http://www.michigan.gov/con

MDHHS is an Equal Opportunity Employer, Services and Program Provider

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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.

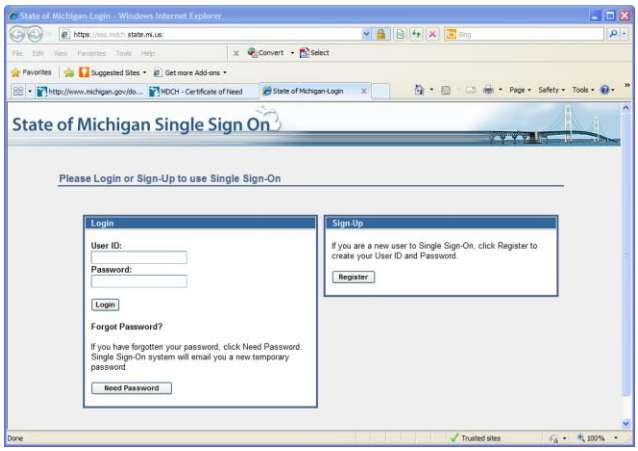
TABLE 1
LETTERS OF INTENT RECEIVED AND PROCESSED WITHIN 15 DAYS
FY2013 - FY2017

	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.



http://www.mi.gov/con

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**.

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 I

	2017						2018					
	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March	April	May	June
Commission Meetings			Meeting			Meeting		Special Meeting	Meeting			Meeting
Bone Marrow Transplantation (BMT) Services				Public Comment for 2018 Review				Discussion				
Cardiac Catheterization Services	SAC Meeting	SAC Meeting	SAC Meeting/ Report	SAC Meeting	SAC Meeting	SAC Meeting/ Report			Report/Draft Language Presented/Potential Proposed Action		Public Hearing	Report/ Final Action
Heart/Lung and Liver Transplantation Services				Public Comment for 2018 Review				Discussion				
Hospital Beds	SAC Meeting	SAC Meeting	SAC Meeting/ Report	SAC Meeting	SAC Meeting	SAC Meeting/ Report			Report/Draft Language Presented/Potential Proposed Action		Public Hearing	Report/ Final Action
Magnetic Resonance Imaging (MRI) Services				Public Comment for 2018 Review				Discussion				
Megavoltage Radiation Therapy (MRT) Services/Units								Discussion/Report				
Open Heart Surgery (OHS)									Report/ Draft Language Presented/Potential Proposed Action			
Psychiatric Beds and Services				Public Comment for 2018 Review				Discussion				
Urinary Extracorporeal Shock Wave Lithotripsy Services		Public Hearing	Report/ Potential Final Action			Report/Draft Language Presented/Proposed Action	Public Hearing		Report/ Final Action			
New Medical Technology Standing Committee	Department Monitoring					Department Monitoring			Department Monitoring			
FY2017 CON Annual Report								Present to Commission				

For Approval February 8, 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 Se (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	2018
Cardiac Catheterization Services	September 14, 2015	2017
Computed Tomography (CT) Scanner Services	December 9, 2016	2019
Heart/Lung and Liver Transplantation Services	September 28, 2012	2018
Hospital Beds	March 20, 2015	2017
Magnetic Resonance Imaging (MRI) Services	October 21, 2016	2018
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	2017
Positron Emission Tomography (PET) Scanner Services	September 14, 2015	2020
Psychiatric Beds and Services	December 9, 2016	2018
Surgical Services	December 22, 2014	2020
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	December 22, 2014	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.