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

Thursday, January 30, 2020

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

APPROVED MINUTES

I. Call to Order

Chairperson Falahee called the meeting to order at 9:33 a.m.

A. Members Present:

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

B. Members Absent:

Melisa Oca, MD

C. Department of Attorney General Staff:

Carl Hammaker

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

Tulika Bhattacharya
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Mittelbrun, 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 5, 2019

Motion by Commissioner Brooks-Williams, seconded by Commissioner Guido-Allen to approve the minutes as presented. Motion carried.

V. Nursing Home and Hospital Long-Term-Care Unit (NH-HLTCU) Beds – Interim Standard Advisory Committee (SAC) Report & Draft Language

NH-HLTCU SAC Chairperson Donald Haney provided the report and presentation (Attachment A).

A. Public Comment

1. Rachel Kelly, Ascension (see written – Attachment B)
2. Peter Massey, Trilogy Health Services (see written – Attachment C)
3. Dalton Herbal, LeadingAge Michigan (see written – Attachment D)

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Mittelbrun, seconded by Commissioner Dood to take proposed action on the language (Attachment E) as presented and move forward to Public Hearing and to the Joint Legislative Committee (JLC). Motion carried in a vote of 9 - Yes, 1 - No, and 0 - Abstained.

VI. Cardiac Catheterization Services – October 4 – 18, 2019 Public Comment Period Summary & Report

A. Public Comment

1. Dr. David Wohns, MI Chapter of ACC & Spectrum Health

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

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner Hughes to accept the Department's recommendation (Attachment F) as presented to continue regulation and to form a SAC to make recommendations for the issues identified; delegate to the chairperson to draft the charge and seat the SAC. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

VII. Hospital Beds – October 4 – 18, 2019 Public Comment Period Summary & Report

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

A. Public Comment

1. Tracey Dietz, Henry Ford Health System

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner Hughes to accept the Department's recommendation (Attachment G) as presented with modification to the observation beds recommendation (evaluate whether observation beds should be included/excluded in the patient count), to continue regulation, and to form a SAC to make recommendations for the issues identified; delegate to the chairperson to draft the charge and seat the SAC. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

VIII. Magnetic Resonance Imaging (MRI) Services – October 4 – 18, 2019 Public Comment Period Summary & Report

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

A. Public Comment

1. Chris Shemes, Sparrow Health System and Sparrow Carson Hospital
2. David Walker, Spectrum Health System

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Wang, seconded by Commissioner McKenzie to accept the Department's recommendation (Attachment H) as presented to continue regulation and to form a workgroup to make recommendations for the issue identified; delegate to the chairperson to draft the charge and appoint a chairperson. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

IX. Megavoltage Radiation Therapy (MRT) Services/Units – October 4 – 18, 2019 Public Comment Period Summary & Report

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

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Gardner, seconded by Commissioner Guido-Allen to accept the Department's recommendation (Attachment I) for no changes at this time. The next scheduled review will be in 2023. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

X. Open Heart Surgery (OHS) Services – October 4 – 18, 2019 Public Comment Period Summary & Report

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

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Guido-Allen, seconded by Commissioner Brooks-Williams to accept the Department's recommendation (Attachment J) for no changes at this time. The next scheduled review will be in 2023. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

XI. Positron Emission Tomography (PET) Scanner Services – October 4 – 18, 2019 Public Comment Period Summary & Report

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

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Gardner, seconded by Commissioner Guido-Allen to accept the Department's recommendation (Attachment K) as presented to continue regulation and to form a workgroup to make recommendations for the issues identified; delegate to the chairperson to draft the charge. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

XII. Surgical Services – October 4 – 18, 2019 Public Comment Period Summary & Report

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

A. Public Comment

1. David Walker, Spectrum Health System

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Gardner, seconded by Commissioner Guido-Allen to accept the Department's recommendation (Attachment L) for no changes at this time. The next scheduled review will be in 2023. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

XIII. FY 2019 CON Annual Activity Report

Ms. Bhattacharya provided an overview of the FY 2019 CON Annual Activity Report (Attachment M).

XIV. Public Comment

None.

Chairperson Falahee provided update on pending legislation.

XV. Review of Commission Work Plan

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

A. Commission Discussion

None.

B. Commission Action

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

XVI. Future Meeting Dates: March 19, 2020, June 18, 2020, September 17, 2020, & December 10, 2020

XVII. Adjournment

Motion by Commissioner Mittelbrun, seconded by Commissioner Lalonde to adjourn the meeting at 11:09 a.m. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

Standards Advisory Committee Report

Nursing Homes and Hospital Long-term Care Units

January 30, 2020

The Nursing Home and Hospital Long-term Care Units (NH/HLTCU) Standards Advisory Committee (SAC) met on December 19, 2019 and January 16, 2020. After first reviewing the Certificate of Need (CON) process involving a SAC and the issues we were asked to address by the CON Commission, the primary focus was the charge to review the bed need methodology. Dr. Paul Delamater, who prepares the bed need report, participated in both meetings by phone.

The initial discussion of the bed need methodology took particular note of the December 3, 2019, NH/HLTCU Bed Need report prepared by Delamater. This report was critical of the current methodology and its ability to accurately predict bed need by planning area. After conducting a test of the current methodology's ability to accurately predict future bed need by using actual past data, the report stated: "Even if presented perfect data, the methodology produces inaccurate results". Because of this, the report strongly recommended modifications to the current methodology.

Based on this report and the initial discussion at the December 19 SAC meeting, I formed a sub-workgroup of the SAC to begin exploring changes to the current methodology. Concerned that the most recent NH/HLTCU bed need report adopted by the CON Commission is based on a seriously flawed methodology--as the Delamater December 3, 2019 report demonstrates--the sub-workgroup met several times over the next few weeks with a sense of urgency to review and discuss a modification to the current methodology that it could recommend to the SAC at its January 16, 2020, meeting. On January 15, after the sub-workgroup had prepared a draft report for the SAC to consider, Beth Nagel of the Michigan Department of Health and Human Services (MDHHS) approached the chair of the sub-workgroup expressing concern that the proposal developed by the sub-workgroup had not been thoroughly studied and reviewed by Dr. Delamater and others. She worked with the chair of the sub-workgroup to develop a modification to the current NH standards, however, that would immediately address the significant negative implications of the most recent bed need report adopted by the commission while at the same time allowing the SAC sufficient time to develop—with Dr. Delamater's assistance—a long term change to the current methodology. The immediate modification is to require that a planning area must have a minimum occupancy rate of 85 percent before beds could be added.

Draft standards language to include this modification was presented to the SAC by the MDHHS and it was adopted unanimously by the SAC, including by all members of the sub-workgroup.

As chair of SAC, I am presenting this recommendation to the CON Commission for consideration and approval. The SAC views this as a temporary "correction" to the current methodology that would best address the severe negative implications of the most recent bed need report, while at the same time allowing the SAC to continue its work on a major change to the bed need methodology utilizing the sub-workgroup and assistance from Dr. Paul Delamater.

Thank you for considering our recommendation.

Ascension

Ascension Michigan
28000 Dequindre Rd
Warren, MI 48092

ascension.org

January 29, 2020

James Falahee
CON Commission Chairperson
Michigan Department of Community Health
Certificate of Need Policy Section
South Grand Building, 5th Floor
333 South Grand Avenue
Lansing, MI 48933

Dear Chairman Falahee and Commission Members,

Ascension Michigan is asking the commission to follow the nursing home SAC recommendation to change the bed need methodology review standards to prevent the addition of 2,813 beds across the state. Additionally, we are in agreement with the temporary measure to add a census requirement immediately to allow beds where needed but not saturate an area where beds are already empty.

It is our belief that the SAC is working to address the deficiencies of the current methodology, using shared principles of ensuring access to quality care, while controlling costs for the state's Medicaid program.

Sincerely,

Alisha Cottrell
VP Advocacy, Ascension Michigan

CC: Laura Caldwell

TRILOGY
HEALTH SERVICES, LLC

January 21, 2020

RE: Forthcoming recommendation from Nursing Home Standards Advisory Committee

Dear Chairperson James Falahee:

Trilogy Health Services provides independent living, assisted living and skilled nursing home housing to people throughout Michigan, Ohio, Indiana and Kentucky. Trilogy was pleased to acquire its first nursing home in Michigan in 2006 and has since opened 11 other campuses with one more currently under construction.

In its experience, Trilogy has found the Michigan Certificate of Need regulatory and application processes to be the most rational and predictable of all the states in which we operate. To date, Michigan's Certificate of Need has offered a fair and reasonable process upon which Trilogy has relied to make investments in its campuses.

Based on the CON Commission's update of the nursing home bed need last September, and after the Commission's reaffirmation of this bed need at its December meeting, Trilogy moved forward with investments in several properties in anticipation of a February CON filing date. These properties are located in counties the CON Commission identified as having a need for additional nursing home beds. This bed need was the result of CON's rational and established bed need methodology that considers population projections and utilization trends. Based on our own market analysis, Trilogy agrees with the CON Commission about this need. We believe these markets will support additional nursing home beds given current use rates and patterns, as well as the predicted growth in seniors who use our facilities.

We are aware that the CON Commission established a CON Standards Advisory Committee to evaluate several issues within the nursing home standards, including the bed need methodology. We have recently learned this SAC intends to bring forward an interim recommendation at the CON Commission's January meeting to add a single change which would require 85% occupancy in a Planning Area for projects wishing to increase beds in a planning area. We do not believe this forthcoming recommendation is rooted in a holistic, thoughtful bed need methodology, but is instead a tacit attempt to suppress the will of the CON Commission to effectuate its September and December bed need decision. The SAC's recommendation effectively commandeers the results of the existing bed need methodology with the intent to thwart applicants in the February application window. We believe this stand

Forum Office Park II, 303 N. Hurstbourne Parkway, Suite 200, Louisville, KY 40222
(502) 412-5847 Phone • (502) 412-0407 Fax

TRILOGY
HEALTH SERVICES, LLC

alone, and temporary measure, would create a poor precedent for CON policy development; approval of this recommendation would reflect poorly on Michigan's currently-rational and predictable CON process.

Trilogy estimates it has spent more than $75,000 investing in land and work related to these future campuses. Our investment was made in good faith in Michigan's CON process. These are very real costs.

We ask the CON Commission to remand this forthcoming recommendation back to the Standards Advisory Committee and to reaffirm the SAC's charge to develop a comprehensive bed need methodology in conjunction with the expertise of Dr. Paul Delamater. We look forward to the SAC bringing a complete and thoughtful recommendation to the CON Commission at its regularly scheduled meeting in March or June.

Sincerely,

Leigh A. Barney

Leigh Ann Barney
President & CEO
Trilogy Health Services, LLC

LeadingAge™ Michigan

Michigan Certificate of Need Commission

Public Comments Nursing Home Bed Need Methodology 2020

LeadingAge Michigan represents the not-for-profit and mission-based senior care providers across the entire system of post-acute and long term services and supports in Michigan. We believe that the current methodology has over-estimated the actual nursing home bed need in Michigan for some time and are pleased that the Nursing Home SAC will be addressing this issue. Dr. Delamater's work has been greatly appreciated as we move forward. In the interim, we strongly support the inclusion of an 85% occupancy rate per planning area before new beds can be approved.

As senior services transition over time, we suggest a detailed review of the nursing home bed need methodology every three years to ensure it continues to serve the needs of Michigan seniors. This review can include data from the Michigan nursing home cost reports as well as the CON Nursing Home Survey. While nursing home occupancy has been declining, population trends will also be dramatically changing in the next several years and our ability to project need will be complicated. We support the use of a population – based system that also reflects actual facility usage over time.

Additionally, while the work of the Commission has focused almost solely on the need for beds, it is also important to note that the purpose of Certificate of Need is to 'ensure availability and accessibility of quality health services at a reasonable cost and within a reasonable geographic proximity for all persons in the state'. Michigan nursing facility providers in general ignore the specialty bed pools, and yet there continues to be need for those unique beds in Michigan. We ask that the Commission in future look to the barriers to use of these beds.

Thank You,

David E. Herbel
President and CEO

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT (HLTCU) BEDS

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval under Part 222 of the Code that involve a) beginning operation of a new nursing home/HLTCU, (b) replacing beds in a nursing home/HLTCU or physically relocating nursing home/HLTCU beds from one licensed site to another geographic location, (c) increasing licensed beds in a nursing home/HLTCU licensed under Part 217 and a HLTCU defined in Section 20106(6), or (d) acquiring a nursing home/HLTCU. Pursuant to the Code, a nursing home/HLTCU is a covered health facility. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(2) An increase in licensed nursing home/HLTCU beds is a change in bed capacity for purposes of Part 222 of the Code.

(3) The physical relocation of nursing home/HLTCU beds from a licensed site to another geographic location is a change in bed capacity for purposes of Part 222 of the Code.

Section 2. Definitions

Sec. 2. (1) As used in these standards:

(a) "Acquisition of an existing nursing home/HLTCU" means the issuance of a new nursing home/HLTCU license as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing licensed and operating nursing home/HLTCU and which does not involve a change in bed capacity of that health facility.

(b) "ADC adjustment factor" means the factor by which the average daily census (ADC), derived during the bed need methodology calculation set forth in Section 3(2)(d) for each planning area, is divided. The ADC adjustment factor is 0.90 for all planning areas.

(c) "Applicant's cash" means the total unrestricted cash, designated funds, and restricted funds reported by the applicant as the source of funds in the application. If the project includes space lease costs, the applicant’s cash includes the contribution designated for the project from the landlord.

(d) "Base year" means 1987 or the most recent year for which verifiable data collected as part of the Michigan Department of Health and Human Services Annual Survey of Long-Term-Care Facilities or other comparable MDHHS survey instrument are available.

(e) "Certificate of Need Commission" or "Commission" means the commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(f) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(g) "Common ownership or control" means a nursing home, regardless of the state in which it is located, that is owned by, is under common control of, or has a common parent as the applicant nursing home pursuant to the definition of common ownership or control utilized by the Department of Licensing and Regulatory Affairs (LARA), Bureau of Health Care Services.

(h) "Comparative group" means the applications which have been grouped for the same type of project in the same planning area or statewide special pool group and which are being reviewed comparatively in accordance with the CON rules.

(i) "Converted space" means existing space in a health facility that is not currently licensed as part of the nursing home/HLTCU and is proposed to be licensed as nursing home or HLTCU space. An example is proposing to license home for the aged space as nursing home space.

(j) "Department" means the Michigan Department of Health and Human Services (MDHHS).

(k) "Department inventory of beds" means the current list, for each planning area maintained on a continuing basis by the Department: (i) licensed nursing home beds and (ii) nursing home beds approved by a valid CON issued under Part 222 of the Code which are not yet licensed. It does not include (a) nursing home beds approved from the statewide pool and (b) short-term nursing care program beds approved pursuant to Section 22210 of the Code, being Section 333.22210 of the Michigan Compiled Laws.

(l) "Existing nursing home beds" means, for a specific planning area, the total of all nursing home beds located within the planning area including: (i) licensed nursing home beds, (ii) nursing home beds approved by a valid CON issued under Part 222 of the Code which are not yet licensed, (iii) proposed nursing home beds under appeal from a final Department decision made under Part 222 or pending a hearing from a proposed decision issued under Part 222 of the Code, and (iv) proposed nursing home beds that are part of a completed application under Part 222 of the Code which is pending final Department decision. (a) Nursing home beds approved from the statewide pool are excluded; and (b) short-term nursing care program beds approved pursuant to Section 22210 of the Code, being Section 333.22210 of the Michigan Compiled Laws, are excluded.

(m) "Health service area" or "HSA" means the geographic area established for a health systems agency pursuant to former Section 1511 of the Public Health Service Act and set forth in Appendix A.

(n) "Hospital long-term-care unit" or "HLTCU" means a nursing care facility, owned and operated by and as part of a hospital, that provides organized nursing care and medical treatment to seven (7) or more unrelated individuals suffering or recovering from illness, injury, or infirmity.

(o) "Licensed only facility" means a licensed nursing home that is not certified for Medicare or Medicaid.

(p) "Licensed site" means the location of the health facility authorized by license and listed on that licensee's certificate of licensure.

(q) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396g and1396i to 1396u.

(r) "New design model" means a nursing home/HLTCU built in accordance with specified design requirements as identified in the applicable sections.

(s) "Nursing home" means a nursing care facility, including a county medical care facility, but excluding a hospital or a facility created by Act No. 152 of the Public Acts of 1885, as amended, being sections 36.1 to 36.12 of the Michigan Compiled Laws, that provides organized nursing care and medical treatment to seven (7) or more unrelated individuals suffering or recovering from illness, injury, or infirmity. This term applies to the licensee only and not the real property owner if different than the licensee.

(t) "Nursing home bed" means a bed in a health facility licensed under Part 217 of the Code or a licensed bed in a hospital long-term-care unit. The term does not include short-term nursing care program beds approved pursuant to Section 22210 of the Code being Section 333.22210 of the Michigan Compiled Laws or beds in health facilities listed in Section 22205(2) of the Code, being Section 333.22205(2) of the Michigan Compiled Laws.

(u) "Occupancy rate" means the percentage which expresses the ratio of the actual number of patient days of care provided divided by the total number of patient days. Total patient days is calculated by summing the number of licensed and/or CON approved but not yet licensed beds and multiplying these beds by the number of days that they were licensed and/or CON approved but not yet licensed. This shall include nursing home beds approved from the statewide pool. Occupancy rates shall be

calculated using verifiable data from the actual number of patient days of care for 12 continuous months of data from the CON Annual Survey or other comparable MDHHS survey instrument.

(v) "Planning area" means the geographic boundaries of each county in Michigan with the exception of: (i) Houghton and Keweenaw counties, which are combined to form one planning area and (ii) Wayne County which is divided into three planning areas. Section 12 identifies the three planning areas in Wayne County and the specific geographic area included in each.

(w) "Planning year" means 1990 or the year in the future, at least three (3) years but no more than seven (7) years, for which nursing home bed needs are developed. The planning year shall be a year for which official population projections, from the Department of Management and Budget or U.S. Census, data are available.

(x) “Proposed licensed site” means the physical location and address (or legal description of property) of the proposed project or within 250 yards of the physical location and address (or legal description of property) and within the same planning area of the proposed project that will be authorized by license and will be listed on that licensee's certificate of licensure.

(y) "Relocation of existing nursing home/HLTCU beds" means a change in the location of existing nursing home/HLTCU beds from the licensed site to a different existing licensed site within the planning area.

(z) "Renewal of lease" means execution of a lease between the licensee and a real property owner in which the total lease costs exceed the capital expenditure threshold.

(aa) "Replacement bed" means a change in the location of the licensed nursing home/HLTCU, the replacement of a portion of the licensed beds at the same licensed site, or the replacement of a portion of the licensed beds pursuant to the new model design. The nursing home/HLTCU beds will be in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, etc.) within the replacement zone.

(bb) "Replacement zone" means a proposed licensed site that is,

(i) for a rural or micropolitan statistical area county, within the same planning area as the existing licensed site.

(ii) for a county that is not a rural or micropolitan statistical area county,

(A) within the same planning area as the existing licensed site and

(B) within a three-mile radius of the existing licensed site.

(cc) "Use rate" means the number of nursing home and hospital long-term-care unit days of care per 1,000 population during a one-year period.

(2) The definitions in Part 222 of the Code shall apply to these standards.

Section 3. Determination of needed nursing home bed supply

Sec. 3 (1)(a) The age specific use rates for the planning year shall be the actual statewide age specific nursing home use rates using data from the base year.

(b) The age cohorts for each planning area shall be: (i) age 0 - 64 years, (ii) age 65 - 74 years, (iii) age 75 - 84 years, and (iv) age 85 and older.

(c) Until the base year is changed by the Commission in accord with Section 4(3) and Section 5, the use rates for the base year per 1000 population for each corresponding age cohort, established in accord with subsection (1)(b), are posted on the State of Michigan CON web site.

(2) The number of nursing home beds needed in a planning area shall be determined by the following formula:

(a) Determine the population for the planning year for each separate planning area in the age cohorts established in subsection (1)(b).

(b) Multiply each population age cohort by the corresponding use rate which is posted on the State of Michigan CON web site.

(c) Sum the patient days resulting from the calculations performed in subsection (b). The resultant figure is the total patient days.

(d) Divide the total patient days obtained in subsection (c) by 365 (or 366 for leap years) to obtain the projected average daily census (ADC).

(e) Divide the ADC determined in subsection (d) by 0.90.

(f) The number determined in subsection (e) represents the number of nursing home beds needed in a planning area for the planning year.

Section 4. Bed need

Sec. 4. (1) The bed need numbers shall apply to project applications subject to review under these standards, except where a specific CON standard states otherwise.

(2) The Department shall apply the bed need methodology in Section 3 on a biennial basis.

(3) The base year and the planning year that shall be utilized in applying the methodology pursuant to subsection (2) shall be set according to the most recent data available to the Department.

(4) The effective date of the bed need numbers shall be established by the Commission.

(5) New bed need numbers established by subsections (2) and (3) shall supersede previous bed need numbers and shall be posted on the state of Michigan CON web site as part of the Nursing Home/HLTCU Bed Inventory.

(6) Modifications made by the Commission pursuant to this section shall not require standard advisory committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to become effective.

Section 5. Modification of the age specific use rates by changing the base year

Sec. 5. (1) The base year shall be modified based on data obtained from the Department and presented to the Commission. The Department shall calculate use rates for each of the age cohorts set forth in Section 3(1)(b) and biennially present the revised use rates based on 2006 information, or the most recent base year information available biennially after 2006, to the CON Commission.

(2) The Commission shall establish the effective date of the modifications made pursuant to subsection (1).

(3) Modifications made by the Commission pursuant to subsection (1) shall not require standard advisory committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to become effective.

Section 6. Requirements for approval to increase beds in a planning area

Sec. 6. An applicant proposing to increase the number of nursing home beds in a planning area must meet the following as applicable:

(1) An applicant proposing to increase the number of nursing home beds in a planning area by beginning operation of a new nursing home/HLTCU or increasing the number of beds to an existing licensed nursing home/HLTCU shall demonstrate the following:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid services.

(vi) Delinquent debt obligation to the State of Michigan including, but not limited to, Quality Assurance Assessment Program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or Civil Monetary Penalties (CMP).

(b) The applicant certifies that the requirements found in the Minimum Design Standards for Health Care Facilities of Michigan, referenced in Section 20145 (6) of the Public Health Code, Act 368 of 1978, as amended and are published by the Department, will be met when the architectural blueprints are submitted for review and approval by the Department.

(c) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

(d) The proposed increase, if approved, will not result in the total number of existing nursing home beds in that planning area exceeding the needed nursing home bed supply, unless one of the following is met:

(i) An applicant may request and be approved for up to a maximum of 20 beds if, when the total number of "existing nursing home beds" is subtracted from the bed need for the planning area, the difference is equal to or more than 1 and equal to or less than 20. This subsection is not applicable to projects seeking approval for beds from the statewide pool of beds.

(ii) An applicant may request and be approved for up to a maximum of 20 beds if the following requirements are met:

(A) The applicant facility has experienced an average occupancy rate of 92% for the most recent 12 consecutive months and 90% or above for the prior 12 months as verifiable by the Department as of the date an application is submitted to the Department.

(B) The applicant facility has not decreased the number of licensed beds within the 24 months preceding the application date.

(C) The applicant facility shall propose no more than two beds per resident room and shall eliminate all three and/or four bed wards within the existing facility, if applicable, as part of the proposed project.

(D) The applicant facility shall certify the new beds for both Medicare and Medicaid.

(E) The applicant facility shall not relocate any beds from the facility or replace a portion of beds to a new site pursuant to Section 7(3)(d), following CON approval and for at least 24 months from the date of the licensure of the new beds at the facility.

(e) THE APPLICANT SHALL DEMONSTRATE THAT THE PLANNING AREA FOR THE PROPOSED PROJECT HAS AN OCCUPANCY RATE OF 85% OR MORE AS PUBLISHED BY THE DEPARTMENT IN THE MOST RECENT CON ANNUAL SURVEY REPORTS.

(2) An applicant proposing to increase the number of nursing home beds in a planning area by beginning operation of a new nursing home/HLTCU or increasing the number of beds to an existing licensed nursing home/HLTCU pursuant to the new design model shall demonstrate the following:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) Delinquent debt obligation to the State of Michigan including, but not limited to, Quality Assurance Assessment Program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or Civil Monetary Penalties (CMP).

(b) The proposed project results in no more than 100 beds per new design model and meets the following design standards:

(i) For inpatient facilities that are not limited to group resident housing of 10 beds or less, the construction standards shall be those applicable to nursing homes in the document entitled Minimum Design Standards for Health Care Facilities in Michigan and incorporated by reference in Section 20145(6) of the Public Health Code, being Section 333.20145(6) of the Michigan Compiled Laws or any future versions.

(ii) For small resident housing units of 10 beds or less that are supported by a central support inpatient facility, the construction standards shall be those applicable to hospice residences providing an inpatient level of care, except that:

(A) at least 100% of all resident sleeping rooms shall meet barrier free requirements;

(B) electronic nurse call systems shall be required in all facilities;

(C) handrails shall be required on both sides of patient corridors; and

(D) ceiling heights shall be a minimum of 7 feet 10 inches.

(iii) The proposed project shall comply with applicable life safety code requirements and shall be fully sprinkled and air conditioned.

(iv) The Department may waive construction requirements for new design model projects if authorized by law.

(c) The proposed project shall include at least 80% single occupancy resident rooms with an adjoining toilet room containing a sink, water closet, and bathing facility and serving no more than two residents in both the central support inpatient facility and any supported small resident housing units.

(d) The proposed increase, if approved, will not result in the total number of existing nursing home beds in that planning area exceeding the needed nursing home bed supply, unless the following is met:

(i) An approved project involves replacement of a portion of the beds of an existing facility at a geographic location within the replacement zone that is not physically connected to the current licensed site. If a portion of the beds are replaced at a location that is not the current licensed site, a separate license shall be issued to the facility at the new location.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

(f) THE APPLICANT SHALL DEMONSTRATE THAT THE PLANNING AREA FOR THE PROPOSED PROJECT HAS AN OCCUPANCY RATE OF 85% OR MORE AS PUBLISHED BY THE DEPARTMENT IN THE MOST RECENT CON ANNUAL SURVEY REPORTS.

Section 7. Requirements for approval to replace beds

Sec. 7. An applicant proposing to replace beds must meet the following as applicable.

(1) An applicant proposing to replace beds within the replacement zone shall not be required to be in compliance with the needed nursing home bed supply if all of the following requirements are met:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control

Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUS and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) Delinquent debt obligation to the State of Michigan including, but not limited to, Quality Assurance Assessment Program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or Civil Monetary Penalties (CMP).

(b) The proposed project is either to replace the licensed nursing home/HLTCU to a new proposed licensed site or replace a portion of the licensed beds at the existing licensed site.

(c) The proposed licensed site is within the replacement zone.

(d) The applicant certifies that the requirements found in the Minimum Design Standards for Health Care Facilities of Michigan, referenced in Section 20145 (6) of the Public Health Code, Act 368 of 1978, as amended and are published by the Department, will be met when the architectural blueprints are submitted for review and approval by the Department.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

(2) An applicant proposing to replace a licensed nursing home/HLTCU outside the replacement zone shall demonstrate all of the following:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control

Applicant with fewer than 10 Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) Delinquent debt obligation to the State of Michigan including, but not limited to, Quality Assurance Assessment Program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or Civil Monetary Penalties (CMP).

(b) The total number of existing nursing home beds in that planning area is equal to or less than the needed nursing home bed supply.

(c) The number of beds to be replaced is equal to or less than the number of currently licensed beds at the nursing home/HLTCU at which the beds proposed for replacement are currently located.

(d) The applicant certifies that the requirements found in the Minimum Design Standards for Health Care Facilities of Michigan, referenced in Section 20145 (6) of the Public Health Code, Act 368 of 1978, as amended and are published by the Department, will be met when the architectural blueprints are submitted for review and approval by the Department.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

(3) An applicant proposing to replace beds with a new design model shall not be required to be in compliance with the needed nursing home bed supply if all of the following requirements are met:

(a) The proposed project results in no more than 100 beds per new design model and meets the following design standards:

(i) For inpatient facilities that are not limited to group resident housing of 10 beds or less, the construction standards shall be those applicable to nursing homes in the document entitled Minimum Design Standards for Health Care Facilities in Michigan and incorporated by reference in Section 20145(6) of the Public Health Code, being Section 333.20145(6) of the Michigan Compiled Laws or any future versions.

(ii) For small resident housing units of 10 beds or less that are supported by a central support inpatient facility, the construction standards shall be those applicable to hospice residences providing an inpatient level of care, except that:

(a) at least 100% of all resident sleeping rooms shall meet barrier free requirements;

(b) electronic nurse call systems shall be required in all facilities;

(c) handrails shall be required on both sides of patient corridors; and
(d) ceiling heights shall be a minimum of 7 feet 10 inches.
(iii) The proposed project shall comply with applicable life safety code requirements and shall be fully sprinkled and air conditioned.
(iv) The Department may waive construction requirements for new design model projects if authorized by law.
(b) The proposed project shall include at least 80% single occupancy resident rooms with an adjoining toilet room containing a sink, water closet, and bathing facility and serving no more than two residents in both the central support inpatient facility and any supported small resident housing units. If the proposed project is for replacement/renovation of an existing facility and utilizes only a portion of its currently licensed beds, the remaining rooms at the existing facility shall not exceed double occupancy.
(c) The proposed project shall be within the replacement zone unless the applicant demonstrates all of the following:
(i) the proposed licensed site for the replacement beds is in the same planning area,
(ii) the applicant shall provide a signed affidavit or resolution from its governing body or authorized agent stating that the proposed licensed site will continue to provide service to the same market, and
(iii) the current patients of the facility/beds being replaced shall be admitted to the replacement beds when the replacement beds are licensed, to the extent that those patients desire to transfer to the replacement facility/beds.
(d) An approved project may involve replacement of a portion of the beds of an existing facility at a geographic location within the replacement zone that is not physically connected to the current licensed site. If a portion of the beds are replaced at a location that is not the current licensed site, a separate license shall be issued to the facility at the new location. If beds have been added pursuant to Section 6(1)(d)(ii), then the applicant facility shall not relocate any beds from the facility or replace a portion of beds to a new site following CON approval and for at least 24 months from the date of the licensure of the new beds at the facility.
(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

Section 8. Requirements for approval to relocate existing nursing home/HLTCU beds

Sec. 8. (1) An applicant proposing to relocate existing nursing home/HLTCU beds shall not be required to be in compliance with the needed nursing home bed supply if all of the following requirements are met:
(a) There shall not be any ownership relationship requirements between the nursing home/HLTCU from which the beds are being relocated and the nursing home/HLTCU receiving the beds.
(b) The relocated beds shall be placed in the same planning area.
(c) The relocated beds shall be licensed to the receiving nursing home/HLTCU and will be counted in the inventory for the applicable planning area.
(d) At the time of transfer to the receiving facility, patients in beds to be relocated must be given the choice of remaining in another bed in the nursing home/HLTCU from which the beds are being transferred or to the receiving nursing home/HLTCU. Patients shall not be involuntary discharged to create a vacant bed.
(e) Relocation of beds shall not increase the rooms with three (3) or more bed wards in the receiving facility.
(f) If beds have been added pursuant to Section 6(1)(d)(ii), then the applicant facility shall not relocate any beds from the facility or replace a portion of beds to a new site following con approval and for at least 24 months from the date of the licensure of the new beds at the facility.

(2) An applicant proposing to add new nursing home/HLTCU beds, as the receiving existing nursing home/HLTCU under subsection (1), shall not be required to be in compliance with the needed nursing home bed supply if all of the following requirements are met:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) Delinquent debt obligation to the State of Michigan including, but not limited to, Quality Assurance Assessment Program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or Civil Monetary Penalties (CMP).

(b) The approval of the proposed new nursing home/HLTCU beds shall not result in an increase in the number of nursing home beds in the planning area.

(c) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

Section 9. Requirements for approval to acquire an existing nursing home/HLTCU or renew the lease of an existing nursing home/HLTCU

Sec. 9. An applicant proposing to acquire an existing nursing home/HLTCU or renew the lease of an existing nursing home/HLTCU must meet the following as applicable:

(1) An applicant proposing to acquire an existing nursing home/HLTCU shall not be required to be in compliance with the needed nursing home bed supply for the planning area in which the nursing home or HLTCU is located if all of the following requirements are met:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) Delinquent debt obligation to the state of Michigan including, but not limited to, quality assurance assessment program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or civil monetary penalties (CMP).

(b) The acquisition will not result in a change in bed capacity.

(c) The licensed site does not change as a result of the acquisition.

(d) The project is limited solely to the acquisition of a nursing home/HLTCU with a valid license.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with the Department, and

(f) The applicant shall participate in a quality improvement program, approved by the Department, for five years and provide an annual report to the Michigan State Long-Term-Care Ombudsman, Bureau of Health Care Services within LARA, and shall post the annual report in the facility if the facility being acquired has met any of conditions in subsections (a)(i), (ii), (iii), (iv), (v), or (vi).

(g) If the applicant is a new entity with no prior NH-HLTCU history, the applicant shall submit proof that:

(i) The nursing home/HLTCU to be acquired is no longer listed as a special focus nursing home by the Center for Medicare and Medicaid Services, or the applicant shall participate in a quality improvement program, approved by the Department, for five years and provide an annual report to the Michigan State Long-Term-Care Ombudsman, Bureau of Health Care Services within LARA, and shall post the annual report in the facility; and

(ii) All delinquent debt obligations to the State of Michigan including, but not limited to, QAAP, PASARR or CMPs have been paid.

(2) An applicant proposing to acquire an existing nursing home/HLTCU approved pursuant to the new design model shall demonstrate the following:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) Delinquent debt obligation to the State of Michigan including, but not limited to, Quality Assurance Assessment Program (QAAP), Preadmission Screening and Annual Resident Review (PASARR) or Civil Monetary Penalties (CMP).

(b) An applicant will continue to operate the existing nursing home/HLTCU pursuant to the new design model requirements.

(c) The applicant shall participate in a quality improvement program, approved by the Department, for five years and provide an annual report to the Michigan State Long-Term-Care Ombudsman, Bureau of Health of Health Care Services within LARA, and shall post the annual report in the facility if the facility being acquired has met any of conditions in subsections (a)(i), (ii), (iii), (iv), (v), or (vi).

(d) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

(e) If the applicant is a new entity with no prior NH-HLTCU history, the applicant shall submit proof that:

(i) The nursing home/HLTCU to be acquired is no longer listed as a special focus nursing home by the Center for Medicare and Medicaid Services, or the applicant shall participate in a quality improvement program, approved by the Department, for five years and provide an annual report to the Michigan State Long-Term-Care Ombudsman, Bureau of Health Care Services within LARA, and shall post the annual report in the facility; and

(ii) All delinquent debt obligations to the State of Michigan including, but not limited to, QAAP, PASARR OR CMPs have been paid.

(3) An applicant proposing to renew the lease for an existing nursing home/HLTCU shall not be required to be in compliance with the needed nursing home bed supply for the planning area in which the nursing home/HLTCU is located, if all of the following requirements are met:

(a) The lease renewal will not result in a change in bed capacity.

(b) The licensed site does not change as a result of the lease renewal.

(c) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Care Services within LARA. Code deficiencies include any unresolved deficiencies still outstanding with LARA.

Section 10. Review standards for comparative review

Sec. 10. (1) Any application subject to comparative review, under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and reviewed comparatively with other applications in accordance with the CON rules.

(2) The degree to which each application in a comparative group meets the criterion set forth in Section 22230 of the Code, being Section 333.22230 of the Michigan Compiled Laws, shall be determined based on the sum of points awarded under subsections (a) and (b).

(a) A qualifying project will be awarded points as follows:

(i) For an existing nursing home/HLTCU, the current percentage of patient days of care reimbursed by Medicaid for the most recent 12 months of operation.

(ii) For a new nursing home/HLTCU, the proposed percentage of patient days of care to be reimbursed by Medicaid in the second 12 months of operation following project completion.

Percentage of Medicaid Patient Days (calculated using total patient days for all existing and proposed beds at the facility)	Points Awarded	
	Existing	Proposed
50 – 69%	4	3
70 – 100%	8	7

(b) A qualifying project will be awarded 10 points if all beds in the proposed project will be dually certified for both Medicare and Medicaid services by the second 12 months of operation.

(3) A qualifying project will have 15 points deducted if the applicant has any of the following at the time the application is submitted:

(a) has been a special focus nursing home/HLTCU within the last three (3) years;

(b) has had more than eight (8) substandard quality of care citations; immediate harm citations, and/or immediate jeopardy citations in the three (3) most recent standard survey cycles (includes intervening abbreviated surveys, standard surveys, and revisits);

(c) has had an involuntary termination or voluntary termination at the threat of a medical assistance provider enrollment and trading partner agreement within the last three (3) years;

(d) has had a state enforcement action resulting in a reduction in license capacity or a ban on admissions within the last three (3) years; or

(e) has any delinquent debt obligation to the state of Michigan including, but not limited to, quality assurance assessment program (QAAP), civil monetary penalties (CMP), Medicaid level of care determination (LOCD), or preadmission screening and annual resident review (PASARR).

(4) A qualifying project will be awarded three (3) points if the applicant provides documentation that it participates or if it proposes to participate in a culture change model, which contains person centered care, ongoing staff training, and measurements of outcomes. An additional five (5) points will be awarded if the culture change model, either currently used or proposed, is a model approved by the Department.

(5) A qualifying project will be awarded points based on the proposed percentage of the "Applicant's cash" to be applied toward funding the total proposed project cost as follows:

Percentage “Applicant’s Cash”	Points Awarded
Over 20%	5
10 – 20%	3
5 – 9%	2

(6) A qualifying project will be awarded four (4) points if the entire existing and proposed nursing home/HLTCU is fully equipped with air conditioning. Fully equipped with air conditioning means meeting the design temperatures in table 6b of the minimum design standards for health care facilities in Michigan and capable of maintaining a temperature of 71 – 81 degrees for the resident unit corridors.

(7) A qualifying project will be awarded six (6) or four (4) points based on only one of the following:

(a) Six (6) points if the proposed project has 100% rooms with dedicated toilet room containing a sink, water closet, and bathing facility or

(b) Four (4) points if the proposed project has 80% private rooms with dedicated toilet room containing a sink, water closet and bathing facility.

(8) A qualifying project will be awarded 10 points if it results in a nursing home/HLTCU with 150 or fewer beds in total.

(9) A qualifying project will be awarded five (5) points if the proposed beds will be housed in new construction.

(10) A qualifying project will be awarded 10 points if the entire existing nursing home/HLTCU and its proposed project will have no more than double occupancy rooms at completion of the project.

(11) A qualifying project will be awarded two (2) points if the existing or proposed nursing home/HLTCU is on or readily accessible to an existing or proposed public transportation route.

(12) A qualifying project will be awarded points for technological innovation as follows:

INNOVATIONS	Points Awarded
The proposed project will have wireless nurse call/paging system including wireless devices carried by direct care staff	1
Wireless internet with resident access to related equipment/device in entire facility	1
An integrated electronic medical records system with point-of-service access capability (including wireless devices) for all disciplines including pharmacy, physician, nursing, and therapy services at the entire existing and proposed nursing home/HLTCU	4
The proposed project will have a backup generator supporting all functions with an on-site or piped-in fuel supply and be capable of providing at least 48 hours of service at full load	4

(13) A qualifying project will be awarded three (3) points if the proposed project includes bariatric rooms as follows: project using 0 – 49 beds will result in at least one (1) bariatric room or project using 50 or more beds will result in at least two (2) bariatric rooms. Bariatric room means the creation of patient room(s) included as part of the CON project, and identified on the architectural schematics, that are designed to accommodate the needs of bariatric patients weighing over 350 pounds. The bariatric patient rooms shall have a larger entrance width for the room and bathroom to accommodate over-sized equipment, and shall include a minimum of a bariatric bed, bariatric toilet, bariatric wheelchair, and a device to assist resident movement (such as a portable or build in lift). If an in-room shower is not included in the bariatric patient room, the main/central shower room that is located on the same floor as the bariatric patient room(s) shall include at least one (1) shower stall that has an opening width and depth that is larger than minimum MI code requirements.

(14) Submission of conflicting information in this section may result in a lower point award. If an application contains conflicting information which could result in a different point value being awarded in this section, the Department will award points based on the lower point value that could be awarded from the conflicting information. For example, if submitted information would result in 6 points being awarded, but other conflicting information would result in 12 points being awarded, then 6 points will be awarded. If the conflicting information does not affect the point value, the Department will award points accordingly. For example, if submitted information would result in 12 points being awarded and other conflicting information would also result in 12 points being awarded, then 12 points will be awarded.

(15) The Department shall approve those qualifying projects which, when taken together, do not exceed the need as defined in Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws, and which have the highest number of points when the results of subsections (2) through (12) are totaled. If two or more qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section 22225(1), in the order in which the applications were received by the Department, based on the date and time stamp on the application when the application is filed.

Section 11. Project delivery requirements and terms of approval

Sec. 11. An applicant shall agree that, if approved, the nursing home/HLTCU services shall be delivered in compliance with the following terms of approval:

(1) Compliance with these standards, including the requirements of Section 10. If an applicant is awarded beds pursuant to Section 10 and representations made in that section, the Department shall monitor compliance with those statements and representations and shall determine actions for non-compliance.

(2) Compliance with the following applicable quality assurance standards:

(a) Compliance with Section 22230 of the Code shall be based on the nursing home's/HLTCU's actual Medicaid participation within the time periods specified in these standards. Compliance with Section 10(2)(a) of these standards shall be determined by comparing the nursing home's/HLTCU's actual patient days reimbursed by Medicaid, as a percentage of the total patient days, with the applicable schedule set forth in Section 10(2)(a) for which the applicant had been awarded points in the comparative review process. If any of the following occurs, an applicant shall be required to be in compliance with the range in the schedule immediately below the range for which points had been awarded in Section 10(2)(a), instead of the range of points for which points had been awarded in the comparative review in order to be found in compliance with Section 22230 of the Code: (i) the average percentage of Medicaid recipients in all nursing homes/HLTCUs in the planning area decreased by at least 10 percent between the second 12 months of operation after project completion and the most recent 12-month period for which data are available, (ii) the actual rate of increase in the Medicaid program per diem reimbursement to the applicant nursing home/HLTCU is less than the annual inflation index for nursing homes/HLTCUs as defined in any current approved Michigan State Plan submitted under Title XIX of the Social Security Act which contains an annual inflation index, or (iii) the actual percentage of the nursing home's/HLTCU's patient days reimbursed by Medicaid (calculated using total patient days for all existing and proposed nursing home beds at the facility) exceeds the statewide average plus 10 percent of the patient days reimbursed by Medicaid for the most recent year for which data are available from the Michigan Department of Health and Human Services [subsection (iii) is applicable only to Section 10(2)(a)]. In evaluating subsection (ii), the Department shall rely on both the annual inflation index and the actual rate increases in per diem reimbursement to the applicant nursing home/HLTCU and/or all nursing homes/HLTCUs in the HSA.

(b) For projects involving the acquisition of a nursing home/HLTCU, the applicant shall agree to maintain the nursing home's/HLTCU's level of Medicaid participation (patient days and new admissions) for the time periods specified in these standards, within the ranges set forth in Section 10(2)(a) for which the seller or other previous owner/lessee had been awarded points in a comparative review.

(c) For projects involving replacement of an existing nursing home/HLTCU, the current patients of the facility/beds being replaced shall be admitted to the replacement beds when the replacement beds are licensed, to the extent that those patients desire to transfer to the replacement facility/beds.

(d) The applicant will assure compliance with Section 20201 of the Code, being Section 333.20201 of the Michigan Compiled Laws.

(3) Compliance with the following access to care requirements:

(a) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

(i) not deny services to any individual based on payor source.

(ii) maintain information by source of payment to indicate the volume of care from each payor and non-payor source provided annually.

(iii) provide services to any individual based on clinical indications of need for the services.

(4) Compliance with the following monitoring and reporting requirements:

(a) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information; operating schedules; and demographic, diagnostic, morbidity, and mortality information, as

well as the volume of care provided to patients from all payor sources. The applicant shall provide the required data on an individual basis for each licensed site, in a format established by the Department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(b) The applicant shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.

(5) An applicant shall agree that, if approved, and material discrepancies are later determined within the reporting of the ownership and citation history of the applicant facility and all nursing homes under common ownership and control that would have resulted in a denial of the application, shall surrender the CON. This does not preclude an applicant from reapplying with corrected information at a later date.

(6) The agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant or its authorized agent.

Section 12. Department inventory of beds

Sec. 12. The Department shall maintain a listing of the Department Inventory of Beds for each planning area.

Section 13. Wayne County planning areas

Sec. 13. (1) For purposes of these standards the cities and/or townships in Wayne County are assigned to the planning areas as follows:

Planning Area 84/Northwest Wayne

Canton Township, Dearborn, Dearborn Heights, Garden City, Inkster, Livonia, Northville (part), Northville Township, Plymouth, Plymouth Township, Redford Township, Wayne, Westland

Planning area 85/Southwest Wayne

Allen Park, Belleville, Brownstown Township, Ecorse, Flat Rock, Gibraltar, Grosse Ile Township, Huron Township, Lincoln Park, Melvindale, River Rouge, Riverview, Rockwood, Romulus, Southgate, Sumpter Township, Taylor, Trenton, Van Buren Township, Woodhaven, Wyandotte

Planning area 86/Detroit

Detroit, Grosse Pointe, Grosse Pointe Township, Grosse Pointe Farms, Grosse Pointe Park, Grosse Pointe Woods, Hamtramck, Harper Woods, Highland Park

Section 14. Effect on prior CON review standards, comparative reviews

Sec. 14. (1) These CON review standards supersede and replace the CON Standards for Nursing Home and Hospital Long-Term-Care Unit (HLTCU) Beds approved by the CON Commission on ~~December 11, 2014~~JUNE 15, 2017 and effective on ~~March 20, 2015~~SEPTEMBER 21, 2017.

(2) Projects reviewed under these standards involving a change in bed capacity shall be subject to comparative review except as follows:

(a) replacement of an existing nursing home/HLTCU being replaced in the replacement zone;

(b) replacement of an existing nursing home/HLTCU pursuant to Section 7(3) and within the same planning area as the existing licensed site;
(c) relocation of existing nursing home/HLTCU beds; or
(d) an increase in beds pursuant to Section 6(1)(d)(ii).

(3) Projects reviewed under these standards that relate solely to the acquisition of an existing nursing home/HLTCU or the renewal of a lease shall not be subject to comparative review.

APPENDIX A

Counties assigned to each of the HSAs are as follows:

HSA	COUNTIES		
1	Livingston	Monroe	St. Clair
	Macomb	Oakland	Washtenaw
	Wayne		
2	Clinton	Hillsdale	Jackson
	Eaton	Ingham	Lenawee
3	Barry	Calhoun	St. Joseph
	Berrien	Cass	Van Buren
	Branch	Kalamazoo	
4	Allegan	Mason	Newaygo
	Ionia	Mecosta	Oceana
	Kent	Montcalm	Osceola
	Lake	Muskegon	Ottawa
5	Genesee	Lapeer	Shiawassee
6	Arenac	Huron	Roscommon
	Bay	Iosco	Saginaw
	Clare	Isabella	Sanilac
	Gladwin	Midland	Tuscola
	Gratiot	Ogemaw	
7	Alcona	Crawford	Missaukee
	Alpena	Emmet	Montmorency
	Antrim	Gd Traverse	Oscoda
	Benzie	Kalkaska	Otsego
	Charlevoix	Leelanau	Presque Isle
	Cheboygan	Manistee	Wexford
8	Alger	Gogebic	Mackinac
	Baraga	Houghton	Marquette
	Chippewa	Iron	Menominee
	Delta	Keweenaw	Ontonagon
	Dickinson	Luce	Schoolcraft

APPENDIX B

Rural Michigan counties are as follows:

Alcona	Gogebic	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Montmorency	Schoolcraft
Emmet	Newaygo	Tuscola
Gladwin	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Hillsdale	Mason
Alpena	Houghton	Mecosta
Benzie	Ionia	Menominee
Branch	Isabella	Missaukee
Chippewa	Kalkaska	St. Joseph
Delta	Keweenaw	Shiawassee
Dickinson	Leelanau	Wexford
Grand Traverse	Lenawee	
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Jackson	Muskegon
Bay	Kalamazoo	Oakland
Berrien	Kent	Ottawa
Calhoun	Lapeer	Saginaw
Cass	Livingston	St. Clair
Clinton	Macomb	Van Buren
Eaton	Midland	Washtenaw
Genesee	Monroe	Wayne
Ingham	Montcalm	

Source:

75 F.R., p. 37245 (June 28, 2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CON REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS
--ADDENDUM FOR SPECIAL POPULATION GROUPS

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability; definitions

Sec. 1. (1) This addendum supplements the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds and shall be used for determining the need for projects established to better meet the needs of special population groups within the long-term care and nursing home populations.

(2) Except as provided in sections 2, 3, 4, 5, 6, 7, and 8 of this addendum, these standards supplement, and do not supersede, the requirements and terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds.

(3) The definitions which apply to the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds shall apply to these standards.

(4) For purposes of this addendum, the following terms are defined:

(a) “Bariatric patient” means a patient weighting over 350 pounds.

(b) “Bariatric room” means the creation of patient room(s) included as part of the CON project, and identified on the architectural schematics, that are designed to accommodate the needs of bariatric patients weighing over 350 pounds. The bariatric patient rooms shall have a larger entrance width for the room and bathroom to accommodate over-sized equipment, and shall include a minimum of a bariatric bed, bariatric toilet, bariatric wheelchair, and a device to assist resident movement (such as a portable or build in lift). If an in-room shower is not included in the bariatric patient room, the main/central shower room that is located on the same floor as the bariatric patient room(s) shall include at least one (1) shower stall that has an opening width and depth that is larger than minimum MI Code requirements.

(c) "Behavioral patient" means an individual that exhibits a history of chronic behavior management problems such as aggressive behavior that puts self or others at risk for harm, or an altered state of consciousness, including paranoia , delusions, and acute confusion.

(d) "Infection control program," means a program that will reduce the risk of the introduction of communicable diseases into a ventilator-dependent unit, provide an active and ongoing surveillance program to detect the presence of communicable diseases in a ventilator-dependent unit, and respond to the presence of communicable diseases within a ventilator-dependent unit so as to minimize the spread of a communicable disease.

(e) "Licensed hospital" means either a hospital licensed under Part 215 of the Code; or a psychiatric hospital or unit licensed pursuant to Act 258 of the Public Acts of 1974, as amended, being sections 330.1001 to 330.2106 of the Michigan Compiled Laws.

(f) "Private residence", means a setting other than a licensed hospital; or a nursing home including a nursing home or part of a nursing home approved pursuant to Section 6.

(g) "Traumatic brain injury (TBI)/spinal cord injury (SCI) patient" means an individual with TBI or SCI that is acquired or due to a traumatic insult to the brain and its related parts that is not of a degenerative or congenital nature. These impairments may be either temporary or permanent and cause partial or total functional disability or psychosocial adjustment.

(h) "Ventilator-dependent patient," means an individual who requires mechanical ventilatory assistance.

Section 2. Requirements for approval -- applicants proposing to increase nursing home beds -- special use exceptions

Sec. 2. A project to increase nursing home beds in a planning area which, if approved, would otherwise cause the total number of nursing home beds in that planning area to exceed the needed nursing home bed supply or cause an increase in an existing excess as determined under the applicable CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds, may nevertheless be approved pursuant to this addendum.

Section 3. Statewide pool for the needs of special population groups within the long-term care and nursing home populations

Sec. 3. (1) A statewide pool of additional nursing home beds of 1,958 beds needed in the state is established to better meet the needs of special population groups within the long-term care and nursing home populations. Beds in the pool shall be allocated as follows:

(a) These categories shall be allocated 1,039 beds and distributed as follows and shall be reduced/redistributed in accordance with subsection (c):

(i) TBI/SCI beds will be allocated 400 beds.

(ii) Behavioral beds will be allocated 400 beds.

(iii) Bariatric beds will be allocated 60 beds.

(iv) Ventilator-dependent beds will be allocated 179 beds.

(b) The following historical categories have been allocated 919 beds. Additional beds shall not be allocated to these categories. If the beds within any of these categories are delicensed, the beds shall be eliminated and not be returned to the statewide pool for special population groups.

(i) Alzheimer's disease has 384 beds.

(ii) Health care needs for skilled nursing care has 173 beds.

(iii) Religious has 292 beds.

(iv) Hospice beds has 70 beds.

(c) The Commission may adjust/redistribute the number of beds available in the statewide pool for the needs of special population groups in subsection (1)(a) concurrent with the biennial recalculation of the statewide nursing home and hospital long-term care unit bed need. Modifying the number of beds available in the statewide pool for the needs of special population groups in subsection (1)(a) pursuant to this section shall not require a public hearing or submittal of the standard to the Legislature and the Governor in order to become effective.

(d) By setting aside these beds from the total statewide pool, the Commission's action applies only to applicants seeking approval of nursing home beds pursuant to sections 4, 5, 6, and 7. It does not preclude the care of these patients in units of hospitals, hospital long-term care units, nursing homes, or other health care settings in compliance with applicable statutory or certification requirements.

(2) Increases in nursing home beds approved under this addendum for special population groups shall not cause planning areas currently showing an unmet bed need to have that need reduced or planning areas showing a current surplus of beds to have that surplus increased.

Section 4. Requirements for approval for beds from the statewide pool for special population groups allocated to TBI/SCI patients

Sec. 4. The CON Commission determines there is a need for beds for applications designed to determine the efficiency and effectiveness of specialized programs for the care and treatment of TBI/SCI patients as compared to serving these needs in general nursing home unit(s).

(1) An applicant proposing to begin operation of a new nursing home/HLTCU or add beds to an existing nursing home/HLTCU under this section shall demonstrate with credible documentation to the satisfaction of the Department each of the following:

(a) The beds will be operated as part of a specialized program exclusively for TBI/SCI patients. At the time an application is submitted, the applicant shall demonstrate that it operates:

(i) A continuum of outpatient treatment, rehabilitative care, and support services for TBI/SCI patients; and

(ii) A transitional living program or contracts with an organization that operates a transitional living program and rehabilitative care for TBI/SCI patients.

(b) The applicant shall submit evidence of accreditation of its existing outpatient and/or residential programs by the Commission on Accreditation of Rehabilitation Facilities (CARF) or another nationally-recognized accreditation organization for rehabilitative care and services.

(c) Within 24-months of accepting its first patient, the applicant shall obtain CARF or another nationally-recognized accreditation organization for the nursing home beds proposed under this subsection.

(d) A floor plan for the proposed physical plant space to house the nursing home beds allocated under this subsection that provides for:

(i) Individual units consisting of 20 beds or less per unit, not to be more than 40 beds per facility.

(ii) Day/dining area within, or immediately adjacent to, the unit(s), which is solely for the use of TBI/SCI patients.

(iii) Direct access to a secure outdoor or indoor area at the facility appropriate for supervised activity.

(e) The applicant proposes programs to promote a culture within the facility that is appropriate for TBI/SCI patients of various ages.

(2) Beds approved under this subsection shall not be converted to or utilized as general nursing home use without a CON for nursing home and hospital long-term care unit beds under the CON review standards for nursing home and hospital long-term care unit beds and shall not be offered to individuals other than TBI/SCI patients.

Section 5. Requirements for approval for beds from the statewide pool for special population groups allocated to behavioral patients

Sec. 5. The CON Commission determines there is a need for beds for applications designed to determine the efficiency and effectiveness of specialized programs for the care and treatment of behavioral patients as compared to serving these needs in general nursing home unit(s).

(1) An applicant proposing to begin operation of a new nursing home/HLTCU or add beds to an existing nursing home/HLTCU under this section shall demonstrate with credible documentation to the satisfaction of the Department each of the following:

(a) Individual units shall consist of 20 beds or less per unit.

(b) The facility shall not be awarded more than 40 beds.

(c) The proposed unit shall have direct access to a secure outdoor or indoor area for supervised activity.

(d) The unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the behavioral patients.

(e) The physical environment of the unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.

(f) Staff will be specially trained in treatment of behavioral patients.

(2) Beds approved under this subsection shall not be converted to or utilized as general nursing home use without a CON for nursing home and hospital long-term care unit beds under the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds.

(3) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

Section 6. Requirements for approval for beds from the statewide pool for special population groups allocated to bariatric patients

Sec. 6. The CON Commission determines there is a need for beds for applications designed to determine the efficiency and effectiveness of specialized programs for the care and treatment of bariatric patients as compared to serving these needs in general nursing home unit(s).

(1) An applicant proposing to begin operation of a new nursing home/HLTCU or add beds to an existing nursing home/HLTCU under this section shall demonstrate, with credible documentation to the satisfaction of the Department, each of the following:

(a) The facility shall not be awarded more than 10 beds.

(b) The facility may place beds throughout the facility for a flexible and seamless inclusive resident design.

(c) The proposed beds shall have adequate access to an outdoor or indoor area for activities with appropriate equipment.

(d) The physical environment of any unit containing bariatric beds shall be designed to facilitate visitors.

(e) The unit/beds shall have available specialty equipment to assist staff in providing care.

(f) The beds shall be located on a ground floor and emergency egress will not require stairways or elevators to exit.

(g) The beds shall be established in either single or double occupancy rooms, there shall be no rooms with more than two beds.

(2) Beds approved under this subsection shall not be converted to or utilized for general nursing home use without a CON for nursing home and hospital long-term care unit beds.

(3) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

Section 7. Requirements for approval for beds from the statewide pool for special population groups allocated to ventilator-dependent patients

Sec. 7. The CON Commission determines there is a need for beds for ventilator-dependent patients within the long-term care and nursing home populations

(1) An applicant proposing to begin operation of a new nursing home/HLTCU or add beds to an existing nursing home/HLTCU under this section shall demonstrate, with credible documentation to the satisfaction of the Department, each of the following:

(a) An applicant proposes a program for caring for ventilator-dependent patients in licensed nursing home beds.

(b) An application proposes no more than 40 beds that will be licensed as nursing home beds.

(c) The proposed unit will serve only ventilator-dependent patients.

(2) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

(3) Beds approved under this subsection shall not be converted to or utilized for general nursing home use without a CON for nursing home and hospital long-term care unit beds.

Section 8. Acquisition of nursing home/HLTCU beds approved pursuant to this addendum

Sec. 8. (1) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to religious shall meet the following:

(a) The applicant is a part of, closely affiliated with, controlled, sanctioned or supported by a recognized religious organization, denomination or federation as evidenced by documentation of its federal tax exempt status as a religious corporation, fund, or foundation under section 501(c)(3) of the United States Internal Revenue Code.

(b) The applicant's patient population includes a majority of members of the religious organization or denomination represented by the sponsoring organization.

(c) The applicant's existing services and/or operations are tailored to meet certain special needs of a specific religion, denomination or order, including unique dietary requirements, or other unique religious needs regarding ceremony, ritual, and organization which cannot be satisfactorily met in a secular setting.

(d) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

(2) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to TBI/SCI shall meet the following:

(a) The beds will be operated as part of a specialized program exclusively for TBI/SCI patients. At the time an application is submitted, the applicant shall demonstrate that it operates:

(i) a continuum of outpatient treatment, rehabilitative care, and support services for TBI/SCI patients; and

(ii) a transitional living program or contracts with an organization that operates a transitional living program and rehabilitative care for TBI/SCI patients.

(b) The applicant shall submit evidence of accreditation of its existing outpatient and/or residential programs by the Commission on Accreditation of Rehabilitation Facilities (CARF) or another nationally-recognized accreditation organization for rehabilitative care and services.

(c) Within 24-months of accepting its first patient, the applicant shall obtain CARF or another nationally-recognized accreditation organization for the nursing home beds proposed under this subsection.

(d) A floor plan for the proposed physical plant space to house the nursing home beds allocated under this subsection that provides for:

(i) Individual units consisting of 20 beds or less per unit, not to be more than 40 beds per facility.

(ii) Day/dining area within, or immediately adjacent to, the unit(s), which is solely for the use of TBI/SCI patients.

(iii) Direct access to a secure outdoor or indoor area at the facility appropriate for supervised activity.

(e) The applicant proposes programs to promote a culture within the facility that is appropriate for TBI/SCI patients of various ages.

(3) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to Alzheimer’s disease shall meet the following:

(a) The beds are part of a specialized program for Alzheimer's disease which will admit and treat only patients which require long-term nursing care and have been appropriately classified as a patient on the Global Deterioration Scale (GDS) for age-associated cognitive decline and Alzheimer's disease as a level 4 (when accompanied by continuous nursing needs), 5, or 6.

(b) The specialized program will participate in the state registry for Alzheimer's disease.

(c) The specialized program shall be attached or geographically adjacent to a licensed nursing home and be no larger than 20 beds in size.

(d) The proposed Alzheimer's unit shall have direct access to a secure outdoor or indoor area at the health facility, appropriate for unsupervised activity.

(e) The Alzheimer's unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the Alzheimer's unit patients.

(f) The physical environment of the Alzheimer's unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.
(g) Staff will be specially trained in Alzheimer's disease treatment.
(h) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

(4) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to behavioral patients shall meet the following:
(a) Individual units shall consist of 20 beds or less per unit.
(b) The facility shall not be awarded more than 40 beds.
(c) The proposed unit shall have direct access to a secure outdoor or indoor area for supervised activity.
(d) The unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the behavioral patients.
(e) The physical environment of the unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.
(f) Staff will be specially trained in treatment of behavioral patients.
(g) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

(5) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to hospice shall meet the following:
(a) An applicant shall be a hospice certified by Medicare pursuant to the code of Federal Regulations, Title 42, Chapter IV, Subpart B (Medicare Programs), Part 418 and shall have been a Medicare certified hospice for at least 24 continuous months prior to the date an application is submitted to the Department.
(b) An applicant shall demonstrate that, during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable data are available to the Department, at least 64% of the total number of hospice days of care provided to all of the clients of the applicant hospice were provided in a private residence.
(c) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

(6) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to bariatric patients shall meet the following:
(a) The facility shall not be awarded more than 10 beds.
(b) The facility may place beds throughout the facility for a flexible and seamless inclusive resident design.
(c) The proposed beds shall have adequate access to an outdoor or indoor area for activities with appropriate equipment.
(d) The physical environment of any unit containing bariatric beds shall be designed to facilitate visitors.
(e) The beds shall have available specialty equipment to assist staff in providing care.
(f) The beds shall be located on a ground floor and emergency egress will not require stairways or elevators to exit.
(g) Beds approved under this subsection shall not be converted to or utilized as general nursing home use without a CON for nursing home and hospital long-term care unit beds under the CON review standards.
(h) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

(7) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to ventilator-dependent patients shall meet the following:

(a) An applicant proposes a program for caring for ventilator-dependent patients in licensed nursing home beds.
(b) An application proposes no more than 40 beds that will be licensed as nursing home beds.
(c) The proposed unit will serve only ventilator-dependent patients.
(d) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

Section 9. Project delivery requirements -- terms of approval for all applicants seeking approval under Section 3(1) of this addendum

Sec. 9. (1) An applicant shall agree that if approved, the services shall be delivered in compliance with the terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds.

(2) An applicant for beds from the statewide pool for special population groups allocated to religious shall agree that, if approved, the services provided by the specialized long-term care beds shall be delivered in compliance with the following term of CON approval:
(a) The applicant shall document, at the end of the third year following initiation of beds approved an annual average occupancy rate of 95 percent or more. If this occupancy rate has not been met, the applicant shall delicense a number of beds necessary to result in a 95 percent occupancy based upon its average daily census for the third full year of operation.
(3) An applicant for beds from the statewide pool for special population groups allocated to Alzheimer’s disease shall agree that if approved:

(a) The beds are part of a specialized program for Alzheimer's disease which will admit and treat only patients which require long-term nursing care and have been appropriately classified as a patient on the Global Deterioration Scale (GDS) for age-associated cognitive decline and Alzheimer's disease as a level 4 (when accompanied by continuous nursing needs), 5, or 6.
(b) The specialized program will participate in the state registry for Alzheimer's disease.
(c) The specialized program shall be attached or geographically adjacent to a licensed nursing home and be no larger than 20 beds in size.
(d) The proposed Alzheimer's unit shall have direct access to a secure outdoor or indoor area at the health facility, appropriate for unsupervised activity.
(e) The Alzheimer's unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the Alzheimer's unit patients.
(f) The physical environment of the Alzheimer's unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.
(g) Staff will be specially trained in Alzheimer's disease treatment.

(4) An applicant for beds from the statewide pool for special population groups allocated to hospice shall agree that, if approved, all beds approved pursuant to that subsection shall be operated in accordance with the following CON terms of approval.
(a) An applicant shall maintain Medicare certification of the hospice program and shall establish and maintain the ability to provide, either directly or through contractual arrangements, hospice services as outlined in the Code of Federal Regulations, Title 42, Chapter IV, Subpart B, Part 418, hospice care.
(b) The proposed project shall be designed to promote a home-like atmosphere that includes accommodations for family members to have overnight stays and participate in family meals at the applicant facility.
(c) An applicant shall not refuse to admit a patient solely on the basis that he/she is HIV positive, has AIDS or has AIDS related complex.
(d) An applicant shall make accommodations to serve patients that are HIV positive, have AIDS or have AIDS related complex in nursing home beds.

(e) An applicant shall make accommodations to serve children and adolescents as well as adults in nursing home beds.

(f) Nursing home beds shall only be used to provide services to individuals suffering from a disease or condition with a terminal prognosis in accordance with Section 21417 of the Code, being Section 333.21417 of the Michigan Compiled Laws.

(g) An applicant shall agree that the nursing home beds shall not be used to serve individuals not meeting the provisions of Section 21417 of the Code, being Section 333.21417 of the Michigan Compiled Laws, unless a separate CON is requested and approved pursuant to applicable CON review standards.

(h) An applicant shall be licensed as a hospice program under Part 214 of the Code, being Section 333.21401 et seq. of the Michigan Compiled Laws.

(i) An applicant shall agree that at least 64% of the total number of hospice days of care provided by the applicant hospice to all of its clients will be provided in a private residence.

(5) An applicant for beds from the statewide pool for special population groups allocated to ventilator-dependent patients shall agree that, if approved, all beds approved pursuant to that subsection shall be operated in accordance with the following CON terms of approval.

(a) An applicant shall staff the proposed ventilator-dependent unit with employees that have been trained in the care and treatment of ventilator-dependent patients and includes at least the following:

(i) A medical director with specialized knowledge, training, and skills in the care of ventilator-dependent patients.

(ii) A program director that is a registered nurse.

(b) An applicant shall make provisions, either directly or through contractual arrangements, for at least the following services:

(i) respiratory therapy.

(ii) occupational and physical therapy.

(iii) psychological services.

(iv) family and patient teaching activities.

(c) An applicant shall establish and maintain written policies and procedures for each of the following:

(i) Patient admission criteria that describe minimum and maximum characteristics for patients appropriate for admission to the ventilator-dependent unit. At a minimum, the criteria shall address the amount of mechanical ventilatory dependency, the required medical stability, and the need for ancillary services.

(ii) The transfer of patients requiring care at other health care facilities.

(iii) Upon admission and periodically thereafter, a comprehensive needs assessment, a treatment plan, and a discharge plan that at a minimum addresses the care needs of a patient following discharge.

(iv) Patient rights and responsibilities in accordance with Sections 20201 and 20202 of the Code, being Sections 333.20201 and 333.20202 of the Michigan Compiled Laws.

(v) The type of ventilatory equipment to be used on the unit and provisions for back-up equipment.

(d) An applicant shall establish and maintain an organized infection control program that has written policies for each of the following:

(i) use of intravenous infusion apparatus, including skin preparation, monitoring skin site, and frequency of tube changes.

(ii) placement and care of urinary catheters.

(iii) care and use of thermometers.

(iv) care and use of tracheostomy devices.

(v) employee personal hygiene.

(vi) aseptic technique.

(vii) care and use of respiratory therapy and related equipment.

(viii) isolation techniques and procedures.

(e) An applicant shall establish a multi-disciplinary infection control committee that meets on at least a monthly basis and includes the director of nursing, the ventilator-dependent unit program director, and representatives from administration, dietary, housekeeping, maintenance, and respiratory therapy.

This subsection does not require a separate committee, if an applicant organization has a standing infection control committee and that committee's charge is amended to include a specific focus on the ventilator-dependent unit.

(f) The proposed ventilator-dependent unit shall have barrier-free access to an outdoor area in the immediate vicinity of the unit.

(g) An applicant shall agree that the beds will not be used to service individuals that are not ventilator-dependent unless a separate CON is requested and approved by the Department pursuant to applicable CON review standards.

(h) An applicant shall provide data to the Department that evaluates the cost efficiencies that result from providing services to ventilator-dependent patients in a hospital.

(6) An applicant for beds from the statewide pool for special population groups allocated to TBI/SCI patients shall agree that if approved:

(a) An applicant shall staff the proposed unit for TBI/SCI patients with employees that have been trained in the care and treatment of such individuals and includes at least the following:

(i) A medical director with specialized knowledge, training, and skills in the care of TBI/SCI patients.

(ii) A program director that is a registered nurse.

(iii) Other professional disciplines required for a multi-disciplinary team approach to care.

(b) An applicant shall establish and maintain written policies and procedures for each of the following:

(i) Patient admission criteria that describe minimum and maximum characteristics for patients appropriate for admission to the unit for TBI/SCI patients. At a minimum, the criteria shall address the required medical stability and the need for ancillary services, including dialysis services.

(ii) The transfer of patients requiring care at other health care facilities, including a transfer agreement with one or more acute-care hospitals in the region to provide emergency medical treatment to any patient who requires such care.

(iii) Upon admission and periodically thereafter, a comprehensive needs assessment, a treatment plan, and a discharge plan that at a minimum addresses the care needs of a patient following discharge, including support services to be provided by transitional living programs or other outpatient programs or services offered as part of a continuum of care to TBI patients by the applicant.

(iv) Utilization review, which shall consider the rehabilitation necessity for the service, quality of patient care, rates of utilization and other considerations generally accepted as appropriate for review.

(v) Quality assurance and assessment program to assure that services furnished to TBI/SCI patients meet professional recognized standards of health care for providers of such services and that such services were reasonable and medically appropriate to the clinical condition of the TBI patient receiving such services.

(7) An applicant for beds from the statewide pool for special population groups allocated to behavioral patients shall agree that if approved:

(a) An applicant shall staff the proposed unit for behavioral patients with employees that have been trained in the care and treatment of such individuals and includes at least the following:

(i) A medical director with specialized knowledge, training, and skills in the care of behavioral patients.

(ii) A program director that is a registered nurse.

(iii) Other professional disciplines required for a multi-disciplinary team approach to care.

(b) An applicant shall establish and maintain written policies and procedures for each of the following:

(i) Patient admission criteria that describe minimum and maximum characteristics for patients appropriate for admission to the unit for behavioral patients.

(ii) The transfer of patients requiring care at other health care facilities, including a transfer agreement with one or more acute-care hospitals in the region to provide emergency medical treatment to any patient who requires such care.

(iii) Utilization review, which shall consider the rehabilitation necessity for the service, quality of patient care, rates of utilization and other considerations generally accepted as appropriate for review.

(iv) quality assurance and assessment program to assure that services furnished to behavioral patients meet professional recognized standards of health care for providers of such services and that such services were reasonable and medically appropriate to the clinical condition of the behavioral patient receiving such services.

(v) Orientation and annual education/competencies for all staff, which shall include care guidelines, specialized communication, and patient safety.

(8) An applicant for beds from the statewide pool for special population groups allocated to bariatric patients shall agree that if approved:

(a) The facility shall not be awarded more than 10 beds.

(b) The facility may place beds throughout the facility for a flexible and seamless inclusive resident design.

(c) The proposed beds shall have adequate access to an outdoor or indoor area for activities with appropriate equipment.

(d) The physical environment of any unit containing bariatric beds shall be designed to facilitate visitors.

(e) The beds shall have available specialty equipment to assist staff in providing care.

(f) The beds shall be located on a ground floor and emergency egress will not require stairways or elevators to exit.

(g) The beds shall be established in either single or double occupancy rooms. There shall be no rooms with more than two beds.

(h) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

Section 10. Comparative reviews, effect on prior CON review standards

Sec. 10. (1) Projects proposed under Section 4 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

(2) Projects proposed under Section 5 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

(3) Projects proposed under Section 6 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

(4) Projects proposed under Section 7 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

(5) These CON review standards supercede and replace the CON Review Standards for Nursing Home and Long-term Care Unit Beds--Addendum for Special Population Groups approved by the Commission on December 11, 2014 and effective on March 20, 2015.

MDHHS Recommendations for CON Standards Scheduled for 2020 Review

Cardiac Catheterization (CC) Services Standards			
Department Recommendations: CC services should continue to be regulated. The Commission should form a standard advisory committee (SAC) to make a recommendation regarding the following identified issues.			
Identified Issues	**Issue Recommended for Substantive Review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Review all minimum volume requirements for initiation, relocation, expansion and maintenance.	Yes.	Form a SAC to make a recommendation.	The volume requirements were last reviewed by a SAC in 2011.
Review increased exceptions for more rural programs where travel would cause increased risk for the patient.	Yes.	Form a SAC to make a recommendation.	The current standards include lower initiation volumes for micropolitan and rural counties for only diagnostic cardiac catheterization services.
Review allowing patent foramen ovale (PFO) closures in facilities without open heart surgery (OHS) per the current consensus statement of SCAI/AAN.	Yes.	Form a SAC to make a recommendation.	
Review if diagnostic cardiac catheterization services should be allowed to be performed in ambulatory surgical centers (ASCs).	Yes.	Form a SAC to make recommendation.	
Determine if elective PCI procedures should be allowed to be performed in ASCs.	Yes.	Form a SAC to make recommendations.	

Review current professional guidelines and the CON standards to evaluate the ability of elective PCI programs to perform left-sided cardiac ablations in the cases where patients have low risk Atrial Fibrillation, left-sided Premature Ventricular Contraction / Ventricular Tachycardia in the absence of severe heart failure, left sided Atrial Tachycardia, and Supraventricular Tachycardia Associated with Wolff-Parkinson-White Syndrome per the Heart Rhythm Society's (HRS) Expert Consensus Statement on Electrophysiology Laboratory Standards.	Yes.	Form a SAC to make a recommendation.	
Pacemakers and implantable cardioverter defibrillator (ICD) implants should be allowed to be performed in ASCs.	Yes.	Form a SAC to make recommendations.	This issue was last reviewed by a SAC in 2017.
Determine if a hospital that provides Primary PCI without on-site OHS should be allowed to perform left-sided cardiac ablation procedures.	Yes.	Form a SAC to make recommendations.	
Other technical edits by the Department if needed.	Yes.	Department will draft any if needed for a SAC to review.	

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 CC Services Standards are scheduled for review in calendar year 2020.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 4 - 18, 2019. Testimony was received from seven organizations and is summarized as follows:

1. *Thomas "Tim" Stover & Alisha Cottrell, Ascension Michigan*
    - Supports continued regulation with no changes.

2. *Patrick O'Donovan, Beaumont Health*
    - Supports continued regulation with no changes.

3. *Barbara Bressack, Henry Ford Health System (HFHS)*
    - Supports continued regulation with no changes.

4. *Sunita Vadakath, MD, MidMichigan Health*
    - Requesting that the minimum volume/procedure equivalent requirements be reviewed in order to maintain adequate cardiac catheterization services for their patients. They state that "300 procedure equivalents is an arbitrary number."
    - They are also proposing increased exceptions for more rural programs where travel would cause increased risk for the patient. It is stated that this will ensure adequate access to quality services is maintained for all of their patients, even in the rural areas.

5. *Kelly Smith, Trinity Health - Michigan*
    - Supports continued regulation.
    - Recommends allowing PFO closures in facilities without open heart surgery per the current consensus statement of SCAI/AAN.
    - Review current professional guidelines and the CON standards to evaluate the ability of elective PCI programs to perform left-sided cardiac ablations in the cases where patients have low risk Atrial Fibrillation, left-sided Premature Ventricular Contraction/Ventricular Tachycardia in the absence of severe heart failure, left sided Atrial Tachycardia, and Supraventricular Tachycardia Associated with Wolff-Parkinson-White Syndrome per the Heart Rhythm Society's (HRS) Expert Consensus Statement on Electrophysiology Laboratory Standards.

6. *T. Anthony Denton, JD, MHA & Hitinder Gurm, MD, University of Michigan Health System (UMHS)*
    - Supports continued regulation.
    - Asking the Commission to consider the following:
        - Diagnostic cardiac catheterization services should be allowed to be performed in ambulatory surgical centers (ASCs).
        - Determine if elective Percutaneous Coronary Intervention (PCI) procedures should be allowed to be performed in ambulatory surgical centers (ASCs).
        - Pacemakers and implantable cardioverter defibrillator (ICD) implants should be allowed to be performed in ambulatory surgical centers (ASCs).
        - Determine if a hospital that provides Primary PCI without on-site OHS

(Open Heart Surgery) should be allowed to perform Left sided cardiac ablation procedures.

Background:

The CC standards were reviewed with a standard advisory committee (SAC) in 2017. The current effective date of the CC standards is December 26, 2018.

CC Survey Data for 2018:

Annual survey data for 2018 is the latest available and can be found here:

Cardiac Catheterization Services – Adult
https://www.michigan.gov/documents/mdhhs/Report_060_Cardiac_Catheterization_Services_Adult_658574_7.pdf

Cardiac Catheterization Services – Pediatric
https://www.michigan.gov/documents/mdhhs/Report_062_Cardiac_Catheterization_Services_Pediatric_658576_7.pdf

MDHHS Recommendations for CON Standards Scheduled for 2020 Review

Hospital Beds Standards			
Department Recommendations: Hospital Beds should continue to be regulated. The Commission should form a Standard Advisory Committee (SAC) to make a recommendation regarding the issues identified below.			
Identified Issues	**Issue Recommended for Substantive Review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Review the requirements and provisions for limited access areas.	Yes.	Form a SAC to address and make recommendations.	Recommended by the Department at the 9/19/19 CON Commission meeting.
Evaluate flexibility in the licensed hospital definition to accommodate shifts in inpatient to outpatient settings given both national and local trends.	No.		The definition of a licensed hospital is found in statute and cannot be modified by the Certificate of Need standards.
Revise definition of Hospital Bed [Section 2(q)] to add language that excludes observation beds.	Yes.	Department can draft language.	Recommended by the Department. There is a concern that hospital providers may be reporting observation bed patient days of care as licensed hospital beds patient days of care, which may be inflating hospital bed utilization.
Add definition “Verifiable data” which is already used in the Surgical Services standards.	No.	Department can draft language.	Recommended by the Department. This is a technical change that clarifies current practice.

Other technical edits by the Department if needed.		Department will draft when necessary.	

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 Hospital Beds Standards are scheduled for review in calendar year 2020.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 4 - 18, 2019. Testimony was received from four organizations and is summarized as follows:

1. *Thomas "Tim" Stover & Alisha Cottrell, Ascension Michigan*
    - Supports continued regulation.
    - Recommends a SAC or workgroup to review the requirements and provisions for limited access areas.

2. *Barbara Bressack, Henry Ford Health System (HFHS)*
    - Supports continued regulation.
    - Recommends a SAC to evaluate flexibility in the licensed hospital definition to accommodate shifts in IP to OP settings given both national and local trends.

3. *Kelly Smith, Trinity Health - Michigan*
    - Supports continued regulation.
    - They support the Commission's decision to review and revise the language and methodology related to Limited Access Areas to ensure the Standard reflects the intended use of the Limited Access Area provision. They further state that it does not require a SAC or workgroup.

4. *T. Anthony Denton, JD, MHA, University of Michigan Health System (UMHS)*
    - Supports continued regulation with no changes.

Background:

The Hospital Beds standards were reviewed with a standard advisory committee (SAC) in 2017. The current effective date of the Hospital Beds standards is November 28, 2018.

Hospital Beds Survey Data for 2018:

Annual survey data for 2018 is the latest available and can be found here:

Hospital Beds by HSA
https://www.michigan.gov/documents/mdhhs/Report_010_Hospital_Beds_by_HSA_658534_7.pdf

Hospital Beds by County
https://www.michigan.gov/documents/mdhhs/Report_011_Hospital_Beds_by_County_658535_7.pdf

Acute Care by HSA
https://www.michigan.gov/documents/mdhhs/Report_020_Acute_Care_by_HSA_658538_7.pdf
Acute Care by County

https://www.michigan.gov/documents/mdhhs/Report_021_Acute_Care_by_County_658539_7.pdf

MDHHS Recommendations for the Review of CON Standards

Magnetic Resonance Imaging (MRI) Services Standards			
Department Recommendations: MRI services should continue to be regulated by CON. The Commission should form a workgroup to make a recommendation regarding the issue outlined below.			
Identified Issues	**Issue Recommended for Substantive Review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Review minimum volume requirements for fixed and mobile MRI.	Yes.	Form a workgroup to make a recommendation.	These standards are scheduled for review in 2021. However, the Commission may choose to review this issue in 2020.
Other technical edits by the Department if needed.		Department will draft language if any.	

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 2021.

Public Comment Period Testimony

The Department held a Public Comment Period on October 4 - 18, 2019 to receive testimony regarding the Standards that are up for review in 2020. Testimony was received from three organizations regarding MRI services and is summarized as follows:

1. *Gregory L. Hedegore, Alliance HNI Health Care Services*
    - Supports continued regulation of MRI services.
    - Recommends lowering the minimum volume requirements of 5,500 adjusted procedures for mobile providers in the project delivery requirements.

2. *Saju George, Garden City Hospital*
    - Supports continued regulation of MRI.
    - Recommends reviewing the minimum volume requirements in the project delivery requirements so that these utilization thresholds are in line with industry practices.

3. *William Roeser, Sparrow Health System*
    - Recommends reviewing the minimum volume requirements in the project delivery requirements and "consider adding a provision to exempt facilities from the minimum volume if they are creating critical geographic access to this service, acknowledging the need for some MRI services to remain in operation, regardless of volume, if their closure would leave a void in the region."

Background:

The MRI Services standards were reviewed by the Department in 2016. The current effective date of the MRI Services standards is October 21, 2016.

MRI Services Survey Data for 2018:

Annual survey data for 2018 is the latest available and can be found here:

MRI Service Utilization Lists
https://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5106-116472--,00.html

Available Adjusted MRI Procedures
https://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5106_37086_38860-116567--,00.html

MDHHS Recommendations for CON Standards Scheduled for 2020 Review

Megavoltage Radiation Therapy (MRT) Services/Units Standards			
Department Recommendations: MRT services/units should continue to be regulated by CON. There are no recommended changes at this time. The next scheduled review will be in 2023.			
Identified Issues	**Issue Recommended for Substantive Review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Review High Megavoltage Radiation Therapy (HMRT) in Section 3(4) of the standards to incorporate current and more relevant standards to support the delivery of health care to cancer patients who may benefit from proton therapy.	No.		An MRT SAC deliberated in 2018, and the new MRT Standards became effective in September of 2019.
Other technical edits by the Department if needed.		Department will draft language if any.	

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 MRT Services/Units Standards are scheduled for review in calendar year 2020.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 4 - 18, 2019. Testimony was received from six organizations and is summarized as follows:

1. *Thomas "Tim" Stover & Alisha Cottrell, Ascension Michigan*
    - Supports continued regulation of MRT services/units and recommends no changes at this time.

2. *Patrick O'Donovan, Beaumont Michigan*
    - Supports continued regulation of MRT services/units and recommends no changes at this time.

3. *Barbara Bressack, Henry Ford Health System (HFHS)*
    - HFHS supports the continued regulation of MRT services/units and recommends no changes at this time.
4. *Mary Kay VanDriel, FACHE, Spectrum Health*
    - Recommends no changes at this time.

5. *Kelly C. Smith, Trinity Health Michigan*
    - Supports continued regulation of MRT services/units and recommends no changes at this time.

6. *T. Anthony Denton, JD, MHA & Theodore S. Lawrence, MD, PhD, University of Michigan Health System (UMHS)*
    - Supports continued regulation of MRT services/units.
    - Recommends the review of High Megavoltage Radiation Therapy (HMRT) in Section 3(4) of the standards to incorporate current and more relevant standards to support the delivery of health care to cancer patients who may benefit from proton therapy.

Background:

The MRT Services/Units standards were reviewed by a standard advisory committee (SAC) in 2018. The current effective date of the MRT Services/Units standards is September 12, 2019.

MRT Services/Units Survey Data for 2018:

Annual survey data for 2018 is the latest available and can be found here:

MRT Units
https://www.michigan.gov/documents/mdhhs/Report_080_MRT_Units_658548_7.pdf

MRT Non-Special Visits
https://www.michigan.gov/documents/mdhhs/Report_082_MRT_Non_Special_Visits_658551_7.pdf

MRT Irradiation Visits
https://www.michigan.gov/documents/mdhhs/Report_085_MRT_Irradiation_Visits_658553_7.pdf

MRT Special Purpose Radiosurgery
https://www.michigan.gov/documents/mdhhs/Report_087_MRT_Special_Purpose_Radiosurgery_658557_7.pdf

MDHHS Recommendations for CON Standards Scheduled for 2020 Review

Open Heart Surgery (OHS) Services Standards
Department Recommendations: OHS services should continue to be regulated by CON. There are no recommended changes at this time. The next review will be in 2023.

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 OHS Services Standards are scheduled for review in calendar year 2020.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 4 - 18, 2019. Testimony was received from four organizations and is summarized as follows:

1. *Thomas "Tim" Stover & Alisha Cottrell, Ascension Michigan*
    - Supports continued regulation of OHS services and recommends no changes at this time.

2. *Barbara Bressack, Henry Ford Health System (HFHS)*
    - HFHS supports the continued regulation of OHS services and recommends no changes at this time.

3. *Kelly C. Smith, Trinity Health Michigan*
    - Supports continued regulation of OHS services and recommends no changes at this time.

Background:

The OHS Services standards were reviewed by the Department in 2017. The current effective date of the OHS Services standards is December 26, 2018.

OHS Services Survey Data for 2018:

Annual survey data for 2018 is the latest available and can be found here:

Open Heart Surgical Utilization
https://www.michigan.gov/documents/mdhhs/Report_070_Open_Heart_Surgical_Utilization_658578_7.pdf

MDHHS Recommendations for CON Standards Scheduled for 2020 Review

Positron Emission Tomography (PET) Services Standards			
Department Recommendations: PET services should continue to be regulated by CON. The Commission should form a workgroup 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**
Review the oversight requirements to initiate mobile and fixed services.	Yes.	Form a workgroup to make a recommendation to the Commission.	
Review minimum volume requirement to convert to a fixed service.	Yes.	Form a workgroup to make a recommendation to the Commission.	Volume requirements were last reviewed in 2011.
Review if utilizing an interim replacement mobile PET unit due to repair of the existing mobile unit, whether a CON should not be required, maybe an LOI waiver or simple notification.	No.		This is not allowable under the statute.
Other technical edits by the Department if needed.		Department will draft language if any.	

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 PET Services Standards are scheduled for review in calendar year 2020.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 4 - 18, 2019. Testimony was received from seven organizations and is summarized as follows:

1. *Gregory L. Hedegore, Alliance HNI Health Care Services*
    - Recommends reviewing the oversight requirements to initiate a mobile PET host site.

2. *Thomas "Tim" Stover & Alisha Cottrell, Ascension Michigan*
    - Supports continued regulation of PET services and recommends no changes at this time.

3. *Patrick O'Donovan, Beaumont Michigan*
    - Supports continued regulation of PET services.
    - Recommends that when utilizing an interim replacement mobile PET unit due to repair of the existing mobile unit, a CON should not be required, maybe an LOI waiver or simple notification. They state "This should apply to interim replacements for all CON covered equipment. This will reduce the potential for interruptions in service for equipment that already has CON approval."

4. *Barbara Bressack, Henry Ford Health System (HFHS)*
    - HFHS supports the continued regulation of PET services and recommends no changes at this time.

5. *Joan Herbert, PharmD, Melwyn Sequeira, MD, and Rod Zapolski, MidMichigan*

    - Recommends that the minimum volume requirement to convert to a fixed service be reviewed.

6. *Kelly C. Smith, Trinity Health Michigan*
    - Supports continued regulation of PET services and recommends no changes at this time.

7. *T. Anthony Denton, JD, University of Michigan Health System (UMHS)*
    - Supports continued regulation of PET services and recommends no changes at this time.

Background:

The PET Services standards were reviewed by the Department in 2014-15. The current effective date of the PET Services standards is September 14, 2015.

PET Services Survey Data for 2018:

Annual survey data for 2018 is the latest available and can be found here:

PET Services - Fixed Scanners
https://www.michigan.gov/documents/mdhhs/Report_141_PET_Services_Fixed_Scanners_658564_7.pdf

PET Services - CSC
https://www.michigan.gov/documents/mdhhs/Report_145_PET_Services_CSC_658565_7.pdf

PET Services - Mobile Routes
https://www.michigan.gov/documents/mdhhs/Report_147_PET_Services_Mobile_Routes_658567_7.pdf

MDHHS Recommendations for CON Standards Scheduled for 2020 Review

Surgical Services Standards			
Department Recommendations: Surgical services should continue to be regulated by CON. There are no recommended changes at this time. The next review will be in 2023.			
Identified Issues	**Issue Recommended for Substantive Review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Review and define what makes a "health system" versus the current "site specific."	No.		Under the CON statue CONs are site specific and CON standards cannot conflict with the statute.
Other technical edits by the Department if needed.		Department will draft language if any.	

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 Surgical Services Standards are scheduled for review in calendar year 2020.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 4 - 18, 2019. Testimony was received from six organizations and is summarized as follows:

1. *Thomas "Tim" Stover & Alisha Cottrell, Ascension Michigan*
    - Supports continued regulation of surgical services and recommends no changes at this time.
2. *Patrick O'Donovan, Beaumont Michigan*
    - Supports continued regulation of surgical services and recommends no changes at this time.
3. *Barbara Bressack, Henry Ford Health System (HFHS)*
    - Supports the continued regulation of surgical services and recommends no changes at this time.
4. *John C. Shull, Spectrum Health*
    - Supports the continued regulation of surgical services and recommends no changes at this time.

5. *Kelly C. Smith, Trinity Health Michigan*
    - Supports continued regulation of surgical services and recommends no changes at this time.

6. *T. Anthony Denton, JD, University of Michigan Health System (UMHS)*
    - Supports continued regulation of surgical services.
    - Recommends a SAC or workgroup to review and define what makes a "health system" versus the current "site specific." They state that "this may be a reasonable discussion to have for other covered services (e.g. MRI, CT)." "Allowing greater geographic planning flexibility to these organizations beyond the current 10-mile (metropolitan) or 20-mile (rural/micropolitan) relocation zones for the replacement of existing licensed Operating Rooms (OR) could be a significant step toward improving access."

Background:

The Surgical Services standards were reviewed by the Department in 2014-15. The current effective date of the Surgical Services standards is November 17, 2017.

Surgical Services Survey Data for 2018:

Annual survey data for 2018 is the latest available and can be found here:

Operating Room Utilization
https://www.michigan.gov/documents/mdhhs/Report_050_Operating_Room_Utilization_658570_7.pdf

Endo, Cysto, and C-Section Utilization
https://www.michigan.gov/documents/mdhhs/Report_051_Endo_Cysto_and_C_Section_Utilization_658572_7.pdf

Attachment M

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) PROGRAM

ANNUAL ACTIVITY REPORT

October 2018 through September 2019
(FY2019)

MDHHS
Michigan Department of Health & Human Services
GRETCHEN WHITMER, GOVERNOR | ROBERT GORDON, DIRECTOR

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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 30th report to the Commission and covers the period beginning October 1, 2018, through September 30, 2019 (FY 2019). 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 2019, the Department has continued to make process improvements in both the Policy and Evaluation Sections.

The Evaluation Section implemented a validation process in the CON Annual Survey for Physician Volume Files related to CT, Cardiac Catheterization, MRT, and Surgical Services to ensure the physician volume files are correct and match the service utilization data entered in the survey. As a result, the 2018 CON Annual Survey had very little errors from providers and the Department was able to publish the survey reports earlier than the previous years. The Department completed statewide compliance review of all facilities providing Lithotripsy, SCN, NICU, MRI and PET Scanner services. The Section also facilitated several webinars to provide up-to-date information on revised CON standards, CON reporting requirements and application processes, and participated in an educational event sponsored by the Department, "Bring Your Child to Work Day" featuring CON related facts in a game format for the children at the CON Booth, which was awarded the third place.

The Policy Section assisted the Commission to make the necessary modifications to the CON Review standards to better reflect practice, improve quality, and add clarity to the standards; revised Cardiac Catheterization Services to better reflect current practice; updated the weights and reduced the maintenance volume for Megavoltage Radiation Therapy (MRT) Services/Units; added replacement requirements to Open Heart Surgery Services to current providers to replace their service to a new location and discontinue service at the previous location; and added requirements for an existing adult inpatient psychiatric service requesting to initiate a child/adolescent inpatient psychiatric service in an over bedded child/adolescent planning area to provide more access to psychiatric beds for child/adolescent patients.

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, Planning and Legislative Services 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 timelines 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 2019 in Review

In FY 2019, there were 365 Letters of Intent received resulting in 210 applications filed for CON review and approval. In addition, the Department received 92 amendments to previously approved applications. In total, the Department approved 224 proposed projects resulting in approximately $1,303,512,386 of new capital expenditures into Michigan's healthcare system. The Department also surveyed 1,066 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 FY2019, the CON Commission revised the review standards for Hospital Beds, Cardiac Catheterization Services, Open Heart Surgery Services, Megavoltage Radiation Therapy (MRT), 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 FY2019.

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 or 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.

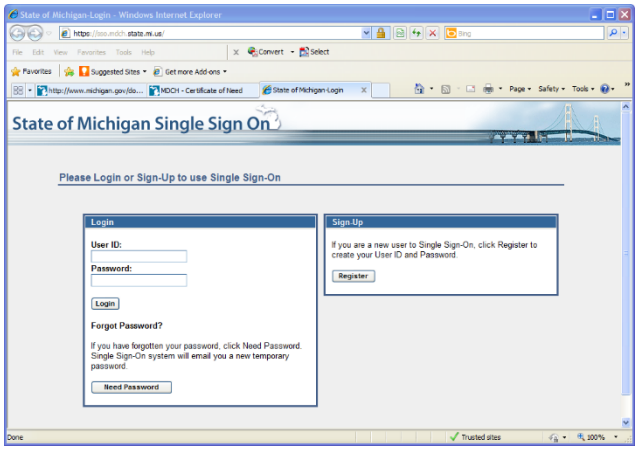
Table 1 provides an overview of the number of LOIs received and processed in accordance with the above-referenced Rule.

TABLE 1
LETTERS OF INTENT RECEIVED AND PROCESSED WITHIN 15 DAYS
FY2015 - FY2019

	LOIs Received	Processed within 15 Days	Percent Processed within 15 Days	Waivers Processed*
FY2015	435	434	99%	44
FY2016	442	439	99%	71
FY2017	341	340	99%	24
FY2018	371	370	99%	73
FY2019	365	363	99%	79

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

In FY 2019, 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 FY2019

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
FY2015 - FY2019

	FY2015	FY2016	FY2017	FY2018	FY2019
Nonsubstantive*	194	171	186	154	132
Substantive Individual	129	148	89	142	72
Comparative	0	0	0	0	6
TOTALS	323	319	275	296	210

* Includes swing bed applications.

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
FY2015 - FY2019

	FY2015	FY2016	FY2017	FY2018	FY2019
Applications Received	326	320	275	296	210
Processed within 15 Days	324	318	272	295	210
Percent Processed within 15 Days	99%	99%	99%	99%	100%

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
FY2015- FY2019

	FY2015	FY2016	FY2017	FY2018	FY2019
Nonsubstantive	42	38	41	36	37
Substantive Individual	112	104	116	102	114
Comparative	N/A	N/A	N/A	N/A	94

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
FY2015 - FY2019

	FY2015	FY2016	FY2017	FY2018	FY2019
Emergency CONs Issued	2	0*	0	0	0
Percent Issued within 10 Working Days	100%	N/A	N/A	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
FY2015- FY2019

	Nonsubstantive		Substantive Individual		Comparative	
	Issued	Issued on Time	Issued	Issued on Time	Issued	Issued on Time
FY2015	195	100%	118	100%	0	N/A
FY2016	169	100%	138	100%	0	N/A
FY2017	167	100%	99	100%	0	N/A
FY2018	174	100%	107	100%	0	N/A
FY2019	123	100%	99	100%	4	100%

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

TABLE 7
COMPARISON OF PROPOSED DECISIONS BY DECISION TYPE
FY2015- FY2019

	Approved	Approved w/ Conditions	Disapproved	Percent Disapproved	TOTAL
FY2015	261	53	1	0.3%	315
FY2016	226	81	0	0%	307
FY2017	205	61	0	0%	266
FY2018	214	65	2	0.7%	281
FY2019	162	62	2*	0.8%	226

Note: Not all proposed decisions issued in a given year will have a final decision in the same year.
** The two (2) proposed decisions for disapproval were for a new nursing with 73 beds in Washtenaw County and a new hospital with 117 beds within Limited Access Area-6 and HSA-1.*

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 FY2015- FY2019*	
FY2015	316
FY2016	303
FY2017	272
FY2018	276
FY2019	224

FIGURE 2
FY 2019 FINAL DECISIONS ISSUED BY HEALTH SERVICE AREAS

Note: Figure 2 does not include 1 out-state decision.

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 projects in the 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 2018, the covered capital expenditure threshold was $3,252,500 and as of January 1, 2019, the covered capital expenditure threshold was increased to $3,325,000. The threshold is updated in January of every year.

TABLE 9 *FINAL DECISIONS ACTIVITY CATEGORY FY2015 - FY2019*					
Approved	**FY2015**	**FY2016**	**FY2017**	**FY2018**	**FY2019**
Acquire, Begin, or Replace a Health Facility	68	26	47	56	27
Change in Bed Capacity	34	42	26	40	40
Covered Clinical Services	214	240	167	180	164
Covered Capital Expenditures	33	49	65	32	36
Disapproved					
Acquire, Begin, or Replace a Health Facility	0	0	0	1	0
Change in Bed Capacity	1	0	0	0	0
Covered Clinical Services	1	0	0	0	0
Covered Capital Expenditures	1	0	0	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 FY2015 - FY2019*				
	Approved	**Approved With Conditions**	**Disapproved**	**Totals**
Number of Final Decisions				
FY2015	261	53	2	316
FY2016	224	79	0	303
FY2017	208	64	0	272
FY2018	210	65	1	276
FY2019	162	62	0	224
Total Project Costs				
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
FY2018	$1,590,933,280	$544,275,880	$ 200,000,000	$2,335,209,160
FY2019	$809,224,031	$494,288,355	$ 0	$1,303,512,386

Note: Final decisions include emergency CON applications.

In FY2019, there was no CON application 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 FY2015 - FY2019				
	Number of Applications	**Difference from Previous Year**	**Total Project Costs**	**Difference from Previous Year**
Letters of Intent Processed				
FY2015	435	31%	$2,894,486,078	126%
FY2016	442	2%	$1,527,863,597	(47%)
FY2017	341	(23%)	$1,864,251,305	22%
FY2018	397	16%	$2,660,753,511	43%
FY2019	365	(8%)	$2,876,054,374	8%
Applications Submitted				
FY2015	326	39%	$2,526,962,926	179%
FY2016	320	(2%)	$1,235,892,460	(51%)
FY2017	275	(14%)	$1,598,240,431	29%
FY2018	296	8%	$2,575,451,177	61%
FY2019	212	(28%)	$1,237,316,450	(52%)
Final Decisions Issued				
FY2015	316	23%	$2,322,741,030	104%
FY2016	303	(4%)	$1,314,654,311	(43%)
FY2017	272	(10%)	$1,376,478,567	5%
FY2018	276	2%	$2,335,209,160	70%
FY2019	224	(18%)	$1,303,512,386	(44%)

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
FY2015 - FY2019

	FY2015	FY2016	FY2017	FY2018	FY2019
Amendments Received	84	76	67	80	92
Amendment Decisions Issued	88	76	68	75	90
Percent Issued within Required Time Frame	100%	97%	100%	100%	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 2019. Seventy (70) of the 224 CON approvals in FY 2019 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
FY2019

Covered Clinical Services/Beds	Existing Sites	Existing Units/Beds	New Sites	New Units/Beds
Air Ambulances	14	17	0	0
Cardiac Catheterization Services	60	231	0	10
Primary PCI	1	N/A	0	N/A
Elective PCI	14	N/A	0	1
Open Heart Surgical Services	34	N/A	0	N/A
Surgical Services	263	1416	12	47
CT Scanners Services	259	398	6	12
MRI Services	295	317	2	0
PET Services	98	27	3	1
Lithotripsy Services	89	11	2	0
MRT Services	69	123	0	1
Transplant Services	6	N/A	0	N/A
Hospitals	185	26,076	0	0
NICU Services	21	640	0	10
SCN Services	15	91	1	6
Extended Care Services Program (Swing Beds)	32	297	0	0
Nursing Homes/HLTCU	472	48,591	2	149
Psychiatric Hospitals/Units	68	2,831	0	100
Psychiatric Flex Beds	4	46	0	0

Note: The source for the existing site and unit/bed information for Table 13 was the 2018 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 2018. New sites include mobile host sites for CT, Lithotripsy, MRI and PET services.

COMPLIANCE ACTIONS

Table 14 shows there were 226 projects requiring follow-up for FY 2019 based on the Department's Monthly Follow-up/Monitoring Report as shown below.

TABLE 14
FOLLOW UP AND COMPLIANCE ACTIONS
FY2015 - FY2019

	FY2015	FY2016	FY2017	FY2018	FY2019
Projects Requiring 1-yr Follow-up	251	314	303	272	226
Approved CONs Expired	95	51	78	118	83
Compliance Orders Issued	30	10	54	48	30

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 statewide compliance review of Lithotripsy, SCN and MRI services. Other compliance orders issued included Air Ambulance, MRT, MRI, Nursing Home 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 3 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 3
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 analyzes the number of applications by fee assessed.

TABLE 15A *NUMBER OF CON APPLICATIONS BY FEE FY2015 – FY2019*					
CON Fee	**FY 2015**	**FY2016**	**FY2017**	**FY2018**	**FY2019**
*$ 0**	6	1	1	1	0
$3,000	146	166	95	123	76
$8,000	91	96	93	86	87
$11,000	36	27	42	30	23
$15,000	47	30	44	54	25
TOTAL	326	320	275	292	211

Note: Table 15A 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 15B analyzes the fees collected for the additional fee categories. More than one fee category may be assessed for one application.

TABLE 15B *NUMBER OF ADDITIONAL CON APPLICATION FEES FY2015 – FY2019*					
CON Fee Category	**FY 2015**	**FY2016**	**FY2017**	**FY2018**	**FY2019**
Complex Project	3	0	9	2	5
Expedited Review	38	42	31	52	47
*LOI Waiver**	34	69	23	77	80
*Amendment**	44	54	56	80	92
Annual Survey (Facilities)	1,107	1,099	1,056	1052	1066

*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 FY2015– FY2019*					
	FY2015	**FY2016**	**FY2017**	**FY2018**	**FY2019**
Program Cost	$2,115,182	$2,051,035	$1,972,166	$2,382,030	$2,114,316
Fees/Funding	$2,620,083	$2,350,168	$2,293,095	$2,607,045	$1,990,861
Fees % of Costs	100%+	100%+	100%+	100%+	94%

Source: MDHHS Budget and Finance Administration.

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY2019, the CON Commission revised the review standards for Hospital Beds, Cardiac Catheterization Services, Open Heart Surgery Services, Megavoltage Radiation Therapy (MRT), and Psychiatric Beds and Services.

The revisions to the CON Review Standards for Hospital Beds received final approval by the CON Commission on June 14, 2018 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 November 28, 2018. The final language changes include the following:

- Updated the Department name throughout the document.
- Section 2(1) - Added and modified definitions as follows:
  - (v) "INPATIENT REHABILITATION FACILITY BED" OR "IRF BED" MEANS A LICENSED HOSPITAL BED WITHIN AN IRF HOSPITAL OR UNIT THAT HAS BEEN APPROVED TO PARTICIPATE IN THE TITLE XVIII (MEDICARE) PROGRAM AS A PROSPECTIVE PAYMENT SYSTEM (PPS) EXEMPT INPATIENT REHABILITATION HOSPITAL IN ACCORDANCE WITH 42 CFR PART 412 SUBPART P.
  - (mm) "RENEWAL OF LEASE" MEANS EXECUTION OF A LEASE BETWEEN THE LICENSEE AND A REAL PROPERTY OWNER IN WHICH THE TOTAL LEASE COSTS EXCEED THE CAPITAL EXPENDITURE THRESHOLD.
  - (oo) "REPLACE IRF BEDS" MEANS A CHANGE IN THE LOCATION OF ALL IRF BEDS FROM AN EXISTING SITE TO A NEW SITE WITHIN THE REPLACEMENT ZONE FOR IRF BEDS.
  - (pp) "Replacement zone" means a proposed licensed site that is (i) in the same hospital group as the existing licensed site as determined by the Department in accord with Section 3 of these standards and (ii) on the same site, on a contiguous site, or on a site within 2 miles (5 MILES FOR IRF BEDS) of the existing licensed site if the existing licensed site is located in a county with a population of 200,000 or more, or on a site within 5 miles (10 MILES FOR IRF BEDS) of the existing licensed site if the existing licensed site is located in a county with a population of less than 200,000.
- Section 6(4)(a) - Added language to allow for beds received under high occupancy to be replaced to a new IRF hospital site under Section 7(6).
  - (a) The beds are being added at the existing licensed hospital site OR ARE BEING REPLACED TO A NEW IRF HOSPITAL SITE BEING CREATED UNDER SECTION 7(7) AS PART OF THE SAME CON APPLICATION.
- Section 6(4)(f) - Removed language that required applicants adding new hospital beds under high occupancy to pursue a good faith effort to relocate acute care beds from other licensed acute care hospitals within the HSA as it's not deemed necessary.
- Section 7 – Added language to replace IRF beds to a new site as follows:
  - (2) The applicant shall specify whether the proposed project is to replace the licensed hospital to a new site, TO REPLACE ALL LICENSED IRF BEDS TO A NEW SITE, to replace a portion of the licensed beds at the existing licensed site, or the one-time replacement of less than 50% of the licensed beds to a new site within 250 yards of the building on the licensed site containing more than 50% of the licensed beds, which may include a new site across a highway(s) or street(s) as defined in MCL 257.20 and excludes a new site across a limited access highway as defined in MCL 257.26.

- (6) IF THE APPLICATION INVOLVES THE DEVELOPMENT OF A NEW LICENSED IRF HOSPITAL SITE, AN APPLICANT PROPOSING TO REPLACE IRF BEDS WITHIN THE REPLACEMENT ZONE SHALL DEMONSTRATE THAT IT MEETS ALL OF THE REQUIREMENTS OF THIS SUBSECTION:
- (a) THE NEW LICENSE CREATED BY THE PROPOSED PROJECT SHALL ONLY BE UTILIZED FOR INPATIENT REHABILITATION BEDS.
- (b) THE APPLICANT HOSPITAL HAS DEMONSTRATED, AT THE TIME OF THE CON FILING, IT IS OPERATING UNDER HIGH OCCUPANCY AS GOVERNED BY SECTION 6(4) OF THESE STANDARDS.
- (c) THE APPLICANT HAS DEMONSTRATED, AT THE TIME OF CON FILING, THAT THE BEDS TO BE REPLACED ARE EITHER IRF BEDS THAT MEET THE TITLE XVIII REQUIREMENTS OF THE SOCIAL SECURITY ACT FOR EXEMPTION FROM PPS AS AN IRF HOSPITAL, OR HIGH OCCUPANCY BEDS BEING REQUESTED UNDER SECTION 6(4) AS PART OF THE SAME CON APPLICATION.
- (d) THE NEW IRF HOSPITAL WILL HAVE AT LEAST 40 IRF BEDS IF LOCATED IN A COUNTY WITH A POPULATION OF 200,000 OR MORE; OR AT LEAST 25 IRF BEDS IF LOCATED IN A COUNTY WITH A POPULATION OF LESS THAN 200,000.
- (e) AS PART OF THE PHASING OF THE REPLACEMENT OF IRF BEDS TO THE NEW SITE, THE APPLICANT MAY RETAIN, FOR 36-MONTHS FROM THE TIME OF ACTIVATION OF THE NEW SITE, UP TO EIGHT IRF BEDS AT THE EXISTING HOSPITAL SITE. ANY IRF BEDS AT THE EXISTING SITE THAT HAVE NOT BEEN TRANSITIONED TO THE NEW SITE WITHIN THE 36-MONTH TIME PERIOD SHALL NOT BE UTILIZED FOR INPATIENT REHABILITATION AND SHALL REVERT BACK TO ACUTE MEDICAL-SURGICAL HOSPITAL BEDS.
- (f) THE PROPOSED PROJECT TO BEGIN OPERATION OF A NEW SITE, UNDER THIS SUBSECTION, SHALL CONSTITUTE A CHANGE IN BED CAPACITY UNDER SECTION 1(2) OF THESE STANDARDS.
- (g) THE EXISTING HOSPITAL SITE SHALL DELICENSE THE SAME NUMBER OF IRF BEDS PROPOSED BY THE APPLICANT FOR LICENSURE IN THE NEW IRF HOSPITAL.
- (h) APPLICANTS PROPOSING A NEW IRF HOSPITAL UNDER THIS SUBSECTION SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW.
- (i) THE NEW IRF HOSPITAL SHALL BE ASSIGNED TO THE SAME HOSPITAL GROUP AS THE HOSPITAL WHERE THE IRF BEDS ORIGINATED.
- (j) IF THE IRF HOSPITAL APPROVED UNDER THIS SUBSECTION CEASES OPERATION AS AN IRF HOSPITAL, THE BEDS LICENSED AS PART OF THE NEW IRF HOSPITAL MUST BE DISPOSED OF BY ONE OF THE FOLLOWING MEANS:
- (i) RELOCATE THE REPLACED IRF BEDS BACK TO THE SITE OF ORIGIN;
- (ii) RELOCATE ALL IRF BEDS APPROVED UNDER HIGH OCCUPANCY TO THE SITE OF ORIGIN IN SUBSECTION (i) IF THEY ARE TO BE UTILIZED AS AN IRF BED; OR
- (iii) DELICENSE ANY IRF BEDS APPROVED UNDER HIGH OCCUPANCY IF THEY ARE NOT TO BE UTILIZED AS AN IRF BED.

➢ Section 9(5) – Added language to the project delivery requirements for replacement of IRF beds to a new site as follows:

- (5) AN APPLICANT APPROVED FOR THE REPLACEMENT OF IRF BEDS UNDER SECTION 7(6) TO A NEW NON-CONTIGUOUS SITE SHALL BE IN COMPLIANCE WITH THE FOLLOWING:

  - (a) THE REPLACED IRF BEDS SHALL MAINTAIN THEIR PPS EXEMPT INPATIENT REHABILITATION HOSPITAL STATUS.
  - (b) THE NEW LICENSE CREATED BY THE PROPOSED PROJECT WILL ONLY BE UTILIZED FOR INPATIENT REHABILITATION BEDS.
- Section 12 – Updated comparative review criteria.
- Old Section 13 – Removed and combined with Section 12.
- New Section 13 – Added language for the renewal of a lease similar to other CON Review Standards.
- New Section 14(4) – Added new language for the applicant to certify that the requirements for hospitals found in the Minimum Design Standards for Health Care Facilities of Michigan will be met when the architectural blueprints are submitted for review and approval by Licensing and Regulatory Affairs (LARA). This is similar to other CON Review Standards.
- Removal of Appendix D Limited Access Areas as it's located on the State of Michigan CON web site. All references have been updated to reflect the State of Michigan CON web site. Appendix E is now Appendix D ICD-9-CM TO ICD-10-CM Code Translation.
- Other technical edits.

The revisions to the CON Review Standards for Cardiac Catheterization Services received final approval by the CON Commission on September 20, 2018 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 26, 2018. The final language changes include the following:

- Updated the Department name throughout the document.
- Added "hospital" after "applicant" throughout the document, as applicable, for clarity.
- Added "/congenital" after "pediatric" throughout the document, as applicable, for clarity.
- Section 2(1) - Added and modified definitions as follows:
  - (a) "ADULT CARDIAC CATHETERIZATION SERVICE" MEANS PROVIDING CARDIAC CATHETERIZATION SERVICES ON AN ORGANIZED, REGULAR BASIS TO PATIENTS AGE 18 AND ABOVE, AND FOR ELECTROPHYSIOLOGY PROCEDURES TO PATIENTS AGE 15 AND OLDER.
  - (b) "Cardiac catheterization laboratory" or "laboratory" means an individual radiological room equipped with a variety of x-ray machines and devices such as electronic image intensifiers, high speed film changers and digital subtraction units to assist in performing diagnostic or therapeutic cardiac catheterizations or electrophysiology studies.
  - (c) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, performed on a patient during a single session in a laboratory. Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X rays and an electronic image intensifier are used as aides in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart. This term does not include "float catheters" that are performed at the bedside or in settings outside the laboratory or the implantation of cardiac permanent pacemakers and implantable cardioverter defibrillators (ICD) devices that are performed in an interventional radiology laboratory or operating room IN A LICENSED HOSPITAL AND HAS DIAGNOSTIC CARDIAC CATHETERIZATION CON APPROVAL.

- (d) "Cardiac catheterization service" means the provision of one or more of the following types of procedures: adult diagnostic cardiac catheterizations; adult therapeutic cardiac catheterizations; and pediatric/CONGENITAL cardiac catheterizations.
- (e) “CARDIAC CATHETERIZATION SESSION” MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC OR THERAPEUTIC CARDIAC OR PERIPHERAL PROCEDURES IN A CARDIAC CATHETERIZATION LABORATORY. THE TERM SESSION APPLIES TO BOTH ADULT AND PEDIATRIC/CONGENITAL CATHETERIZATIONS.
- (h) “COMPLEX THERAPEUTIC SESSION” MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT UNDERGOES ONE OR MORE OF THE FOLLOWING PROCEDURES:
  (i) PCI FOR CHRONIC TOTAL OCCLUSION
  (ii) TAVR, MITRAL/PULMONARY/TRICUSPID VALVE REPAIR OR REPLACEMENT, PARAVALVULAR LEAK CLOSURE
  (iii) ABLATION FOR ATRIAL FIBRILLATION (AF) OR VENTRICULAR TACHYCARDIA (VT), PACEMAKER OR ICD LEAD EXTRACTION
- (j) “DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURE” INCLUDES RIGHT HEART CATHETERIZATION, LEFT HEART CATHETERIZATION, CORONARY ANGIOGRAPHY, CORONARY ARTERY BYPASS GRAFT ANGIOGRAPHY, INTRACORONARY ADMINISTRATION OF DRUGS, FRACTIONAL FLOW RESERVE (FFR), INTRA-CORONARY IMAGING SUCH AS INTRAVASCULAR ULTRASOUND (IVUS), OPTICAL COHERENCE TOMOGRAPHY (OCT), OR NEAR-INFRARED SPECTROSCOPY (NIRS) WHEN PERFORMED WITHOUT A THERAPEUTIC PROCEDURE, CARDIAC BIOPSY, INTRA-CARDIAC ECHOCARDIOGRAPHY, AND ELECTROPHYSIOLOGY STUDY.
- (k) "Diagnostic cardiac catheterization service" means providing diagnostic cardiac catheterization procedures on an organized, regular basis in a laboratory to diagnose anatomical and/or physiological problems in the heart. Procedures include the intra coronary administration of drugs; left heart catheterization; right heart catheterization; coronary angiography; diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic). A hospital that provides diagnostic cardiac catheterization services may also perform implantations of cardiac permanent pacemakers and ICD devices IMPLANTATION (THERAPEUTIC PROCEDURES).
- (l) “DIAGNOSTIC CARDIAC CATHETERIZATION SESSION” MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES.
- (m) “DIAGNOSTIC PERIPHERAL PROCEDURE” INCLUDES ANGIOGRAPHY OR HEMODYNAMIC MEASUREMENTS IN THE ARTERIAL OR VENOUS CIRCULATION (EXCLUDING THE HEART).
- (n) “DIAGNOSTIC PERIPHERAL SESSION” MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC PERIPHERAL ROCEDURES IN A CARDIAC CATHETERIZATION LABORATORY.
- (p) “Elective PCI services without on-site open heart surgery (OHS)” means performing PCI, percutaneous transluminal coronary angioplasty (PTCA), and coronary stent implantation on an organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary PCI service but not having OHS on-site and adhering to patient selection as outlined in the SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site Surgical

Backup and published in Circulation 2014, 129:2610-2626 and its update or further guideline changes. A HOSPITAL THAT PROVIDES ELECTIVE PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM RIGHT-SIDED CARDIAC ABLATION PROCEDURES INCLUDING RIGHT ATRIAL FLUTTER, AV REENTRY, AV NODE REENTRY, RIGHT ATRIAL TACHYCARDIA, AND AV NODE ABLATION.

- (t) "Pediatric/CONGENITAL cardiac catheterization service" means providing cardiac AND ELECTROPHYSIOLOGY catheterization services on an organized, regular basis to infants and children ages 18 and below, except for electrophysiology studies that are offered and provided to infants and children ages 14 and below, and PATIENTS BORN with congenital heart disease.
- (u) "PERCUTANEOUS CORONARY INTERVENTION" (PCI) MEANS A THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURE TO RESOLVE ANATOMIC AND/OR PHYSIOLOGIC PROBLEMS IN THE CORONARY ARTERIES OF THE HEART. A PCI SESSION MAY INCLUDE SEVERAL PROCEDURES INCLUDING BALLOON ANGIOPLASTY, ATHERECTOMY, LASER, STENT IMPLANTATION AND THROMBECTOMY. THE TERM DOES NOT INCLUDE THE INTRACORONARY ADMINISTRATION OF DRUGS, FFR OR IVUS WHERE THESE ARE THE ONLY PROCEDURES PERFORMED.
- (v) "PERIPHERAL CATHETERIZATION SESSION" MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE DIAGNOSTIC OR THERAPEUTIC PROCEDURES IN THE ARTERIAL OR VENOUS CIRCULATION (EXCLUDING THE HEART) WHEN PERFORMED IN A CARDIAC CATHETERIZATION LABORATORY.
- (w) "Primary percutaneous coronary intervention (PCI)" means a PCI performed on an EMERGENT BASIS ON A acute myocardial infarction (AMI) patient with confirmed ST-SEGMENT elevation, or new left bundle branch block on an emergent basis, ECG EVIDENCE OF TRUE POSTERIOR MI, OR CARDIOGENIC SHOCK.
- (x) "Primary PCI service without on-site OHS" means performing primary PCI on an emergent basis in a hospital having a diagnostic cardiac catheterization service. A HOSPITAL THAT PROVIDES PRIMARY PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM RIGHT-SIDED CARDIAC ABLATION PROCEDURES INCLUDING RIGHT ATRIAL FLUTTER, AV REENTRY, AV NODE REENTRY, RIGHT ATRIAL TACHYCARDIA, AND AV NODE ABLATION.
- (y) "Procedure equivalent" means a unit of measure that reflects the relative average length of time one patient spends in one session in a CARDIAC CATHETERIZATION laboratory based on the type of procedures being performed. IF A DIAGNOSTIC AND THERAPEUTIC PROCEDURE IS PERFORMED IN THE SAME SESSION, THE HIGHER PROCEDURE EQUIVALENT WEIGHTING WILL BE USED TO EVALUATE UTILIZATION.
- (z) "STRUCTURAL HEART PROCEDURE" MEANS A THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURE TO RESOLVE ANATOMIC AND/OR PHYSIOLOGIC PROBLEMS OF THE HEART VALVES OR CHAMBERS. PROCEDURES INCLUDE: BALLOON VALVULOPLASTY, BALLOON ATRIAL SEPTOSTOMY, TRANSCATHETER VALVE REPAIR, TRANSCATHETER VALVE IMPLANTATION, PARAVALULAR LEAK CLOSURE, LEFT ATRIAL APPENDAGE OCCLUSION, PFO/ASD/VSD/PDA CLOSURE, ALCOHOL ABLATION OF CARDIAC TISSUE, EMBOLIZATION OF CORONARY FISTULAE AND ABNORMAL VASCULAR CONNECTIONS IN THE HEART.
- (aa) "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or physiological problems in the heart.

- (bb) "THERAPEUTIC CARDIAC CATHETERIZATION SESSION" MAY INCLUDE: PCI (ELECTIVE, EMERGENT), PERICARDIOCENTESIS, PERMANENT PACEMAKER IMPLANTATION, ICD IMPLANTATION (ENDOVASCULAR OR SUBCUTANEOUS), PACEMAKER OR ICD GENERATOR CHANGE, PACEMAKER OR ICD LEAD REVISION, CARDIAC ABLATION, AND/OR STRUCTURAL HEART PROCEDURE. THIS ALSO INCLUDES IMPLANTATION OF A CIRCULATORY SUPPORT DEVICE SUCH AS IABP, IMPELLA, ECMO OR TANDEMHEART WHERE THIS IS THE ONLY THERAPEUTIC PROCEDURE. WHEN PCI IS PERFORMED IN MORE THAN ONE CORONARY ARTERY DURING THE SAME SETTING, THIS IS COUNTED AS ONE SESSION.
- (cc) "THERAPEUTIC PERIPHERAL PROCEDURE" MEANS A THERAPEUTIC CATHETERIZATION PROCEDURE TO RESOLVE ANATOMIC AND/OR PHYSIOLOGIC PROBLEMS IN THE ARTERIAL OR VENOUS CIRCULATION (EXCLUDING THE HEART). PROCEDURES MAY INCLUDE PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA), ATHERECTOMY, DRUG ELUTING BALLOON, LASER, STENT IMPLANTATION, IVC FILTER IMPLANTATION OR RETRIEVAL, CATHETER-DIRECTED ULTRASOUND/THROMBOLYSIS, AND THROMBECTOMY.
- (dd) "THERAPEUTIC PERIPHERAL SESSION" MEANS A CONTINUOUS TIME PERIOD DURING WHICH A PATIENT MAY UNDERGO ONE OR MORE THERAPEUTIC PERIPHERAL PROCEDURES IN A CARDIAC CATHETERIZATION LABORATORY.
- (ee) "THERAPEUTIC PEDIATRIC/CONGENITAL CARDIAC CATHETERIZATION SESSION" MAY INCLUDE: STRUCTURAL HEART PROCEDURE (AS LISTED ABOVE), PULMONARY ARTERY ANGIOPLASTY/STENT IMPLANTATION, PULMONARY VALVE PERFORATION, ANGIOPLASTY/STENT IMPLANTATION FOR AORTIC COARCTATION, CARDIAC ABLATION, PACEMAKER/ICD IMPLANTATION, AND PCI.

- Section 5(3) - Added language to replace a cardiac catheterization service to a new site simultaneously with an open heart surgery service. (This language will only apply to those cardiac catheterization services that are being replaced simultaneously with an open heart surgery service. An open heart surgery service must have a diagnostic and therapeutic cardiac catheterization service.)
- Section 10(2) – Project delivery requirements have been updated.
  - (d) EACH PHYSICIAN CREDENTIALED BY A HOSPITAL TO PERFORM DIAGNOSTIC LEFT-HEART CATHETERIZATION AND/OR CORONARY ANGIOGRAPHY MUST PERFORM, AS THE PRIMARY OPERATOR, AN AVERAGE OF AT LEAST 50 DIAGNOSTIC CARDIAC CATHETERIZATION SESSIONS INVOLVING A LEFT-HEART CATHETERIZATION OR CORONARY ANGIOGRAPHY PER YEAR AVERAGED OVER THE MOST RECENT 2 YEARS STARTING IN THE SECOND 12 MONTHS AFTER BEING CREDENTIALED. THIS TWO YEAR AVERAGE WILL BE EVALUATED ON A ROLLING BASIS ANNUALLY THEREAFTER. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS A CARDIAC CATHETERIZATION SESSION IN WHICH THAT PHYSICIAN PERFORMED, AS THE PRIMARY OPERATOR, AT LEAST ONE LEFT-HEART CATHETERIZATION OR CORONARY ANGIOGRAPHY, IN ANY COMBINATION OF HOSPITALS. PHYSICIANS FALLING BELOW THIS VOLUME REQUIREMENT MUST BE PLACED ON A FOCUSED PROFESSIONAL PRACTICE EVALUATION (FPPE) PLAN, WHICH MUST INCLUDE AN INDEPENDENT REVIEW OF ALL DIAGNOSTIC CARDIAC CATHETERIZATION SESSIONS BY AN APPROPRIATE DESIGNEE, TO ENSURE QUALITY OUTCOMES ARE MAINTAINED. IN THE

EVENT A PHYSICIAN DOES NOT PERFORM CARDIAC CATHETERIZATION PROCEDURES ON A TEMPORARY OR PERMANENT BASIS FOR A PERIOD OF 3 MONTHS OR MORE, THE PHYSICIAN DIAGNOSTIC PROCEDURE VOLUME WILL BE ANNUALIZED ON THE 24 MONTH PERIOD PRECEDING THE ABSENCE. WHEN A DIAGNOSTIC CARDIAC CATHETERIZATION SESSION AND AD HOC THERAPEUTIC CARDIAC CATHETERIZATION SESSION ARE PERFORMED TOGETHER, DIAGNOSTIC AND THERAPEUTIC SESSIONS ARE COUNTED SEPARATELY FOR THE PURPOSES OF THIS SUBSECTION. IF A PHYSICIAN IS DOING RIGHT HEART ONLY PROCEDURES, THEN THEY ARE NOT REQUIRED TO MEET THIS VOLUME REQUIREMENT. PHYSICIANS WHO ARE CREDENTIALED BY A HOSPITAL TO PERFORM ADULT THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES ARE NOT REQUIRED TO MEET THE VOLUME REQUIREMENT FOR DIAGNOSTIC CARDIAC CATHETERIZATION SESSIONS.

- (e) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization procedures shall perform, as the primary operator, aN AVERAGE of AT LEAST 50 adult therapeutic cardiac catheterization SESSIONS per year AVERAGED OVER THE MOST RECENT TWO YEARS STARTING in the second 12 months after being credentialed. THIS TWO-YEAR AVERAGE WILL BE EVALUATED ON A ROLLING BASIS annually thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization SESSIONS performed by that physician in any combination of hospitals. PHYSICIANS FALLING BELOW THIS VOLUME REQUIREMENT MUST BE PLACED ON A FOCUSED PROFESSIONAL PRACTICE EVALUATION (FPPE) PLAN, WHICH MUST INCLUDE AN INDEPENDENT REVIEW OF ALL THERAPEUTIC CARDIAC CATHETERIZATION SESSIONS BY AN APPROPRIATE DESIGNEE, TO ENSURE QUALITY OUTCOMES ARE MAINTAINED. IN THE EVENT A PHYSICIAN DOES NOT PERFORM CARDIAC CATHETERIZATION PROCEDURES ON A TEMPORARY OR PERMANENT BASIS FOR A PERIOD OF 3 MONTHS OR MORE, THE PHYSICIAN THERAPEUTIC PROCEDURE VOLUME WILL BE ANNUALIZED ON THE 24-MONTH PERIOD PRECEDING THE ABSENCE. WHEN A DIAGNOSTIC CARDIAC CATHETERIZATION SESSION AND AD HOC THERAPEUTIC CARDIAC CATHETERIZATION SESSION ARE PERFORMED TOGETHER, DIAGNOSTIC AND THERAPEUTIC SESSIONS ARE COUNTED SEPARATELY FOR THE PURPOSES OF THIS SUBSECTION (THIS INCLUDES INTERVENTIONAL CARDIOLOGISTS AND ELECTROPHYSIOLOGISTS). FOR INTERVENTIONAL CARDIOLOGISTS, THE THERAPEUTIC SESSION VOLUME EXCLUDES PACEMAKER AND ICD IMPLANTATION. FOR ELECTROPHYSIOLOGISTS, PACEMAKER AND ICD IMPLANTS PERFORMED IN AN OPERATING ROOM MAY ALSO BE COUNTED TOWARD THE PHYSICIAN THERAPEUTIC VOLUME.
- (f) Each physician credentialed by a hospital to perform pediatric/CONGENITAL cardiac catheterizations shall perform, as the primary operator, aN AVERAGE of AT LEAST 50 pediatric/CONGENITAL cardiac catheterization SESSIONS per year AVERAGED OVER THE MOST RECENT 2 YEARS STARTING in the second 12 months after being credentialed. THIS TWO-YEAR AVERAGE WILL BE EVALUATED ON A ROLLING BASIS and annually thereafter. The annual case load for a physician means pediatric/CONGENITAL cardiac catheterization SESSIONS performed by that physician in any combination of hospitals. PHYSICIANS FALLING BELOW THIS VOLUME REQUIREMENT MUST BE PLACED ON A FOCUSED PROFESSIONAL PRACTICE EVALUATION (FPPE) PLAN, WHICH MUST INCLUDE AN INDEPENDENT REVIEW OF ALL CARDIAC CATHETERIZATION SESSIONS BY AN APPROPRIATE DESIGNEE, TO

ENSURE QUALITY OUTCOMES ARE MAINTAINED. IN THE EVENT A PHYSICIAN DOES NOT PERFORM CARDIAC CATHETERIZATION PROCEDURES ON A TEMPORARY OR PERMANENT BASIS FOR A PERIOD OF 3 MONTHS OR MORE, THE PHYSICIAN THERAPEUTIC PROCEDURE VOLUME WILL BE ANNUALIZED ON THE 24 MONTH PERIOD PRECEDING THE ABSENCE.

- (g) An adult diagnostic cardiac catheterization service shall have a minimum of two appropriately trained physicians on its active hospital staff MEETING THE FOLLOWING CRITERIA:
  (i) are trained consistent with the recommendations of the American College of Cardiology;
  (ii) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and
  (iii) have performed a minimum of 100 adult diagnostic cardiac catheterization SESSIONS in the preceding 12 months. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS A CARDIAC CATHETERIZATION SESSION IN WHICH THAT PHYSICIAN PERFORMED, AS THE PRIMARY OPERATOR, AT LEAST ONE DIAGNOSTIC CARDIAC CATHETERIZATION, IN ANY COMBINATION OF HOSPITALS.
- (h) An adult therapeutic cardiac catheterization service shall have a minimum of two appropriately trained physicians on its active hospital staff MEETING THE FOLLOWING CRITERIA:
  (i) are trained consistent with the recommendations of the American College of Cardiology;
  (ii) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and
  (iii) have performed a minimum of 50 adult therapeutic cardiac catheterization procedures SESSIONS in the preceding 12 months. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS A CARDIAC CATHETERIZATION SESSION IN WHICH THAT PHYSICIAN PERFORMED, AS THE PRIMARY OPERATOR, AT LEAST ONE THERAPEUTIC CARDIAC CATHETERIZATION, IN ANY COMBINATION OF HOSPITALS.
- (i) A pediatric/CONGENITAL cardiac catheterization service shall have AT LEAST ONE physician on its active hospital staff MEETING THE FOLLOWING CRITERIA:

- Section 10(5) – Language has been updated to exclude patients with cardiogenic shock.
- Section 10(5)(f) – Modified language to make it applicable to only those catheterization labs providing primary PCI services without on-site OHS service and for catheterization labs providing elective PCI services without on-site OHS service.
- Section 10(5)(i) – Modified language for clarity.
- Section 11 – Updated procedure type, procedure equivalent, and added a description for the procedure type.
- Removed Appendix B as it's no longer needed given the revised definition for "pediatric/congenital cardiac catheterization service."
- Other technical edits.

The revisions to the CON Review Standards for Open Heart Services received final approval by the CON Commission on September 20, 2018 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 26, 2018. The final language changes include the following:

- Updated the Department name throughout the document.

- Added language under new Section 4 – Requirements to replace an existing OHS Service. This language will not increase the number of OHS services in the state, instead it will allow current OHS providers to replace their service to a new location and discontinue service at the previous location. This language is consistent with language in other CON review standards.
  - (i) A pediatric/CONGENITAL cardiac catheterization service shall have AT LEAST ONE physician on its active hospital staff MEETING THE FOLLOWING CRITERIA:
  - SEC. 4. REPLACE AN EXISTING ADULT OR PEDIATRIC OHS SERVICE MEANS RELOCATING AN EXISTING ADULT OR PEDIATRIC OHS SERVICE TO A NEW GEOGRAPHIC LOCATION OF AN EXISTING LICENSED HOSPITAL. THE TERM DOES NOT INCLUDE THE REPLACEMENT OF AN EXISTING OHS SERVICE AT THE SAME SITE. AN APPLICANT REQUESTING TO REPLACE AN EXISTING OHS SERVICE SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.
  - (1) AN APPLICANT PROPOSING TO REPLACE AN EXISTING OHS SERVICE SHALL DEMONSTRATE THE FOLLOWING:
  - (a) THE EXISTING OHS SERVICE TO BE REPLACED HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.
  - (b) THE PROPOSED NEW SITE IS A HOSPITAL THAT IS OWNED BY, IS UNDER COMMON CONTROL OF, OR HAS A COMMON PARENT AS THE APPLICANT HOSPITAL.
  - (c) THE APPLICANT IS REPLACING THE OHS SERVICE SIMULTANEOUSLY WITH REPLACEMENT OF ITS CARDIAC CATHETERIZATION SERVICE(S) AT THE SAME LOCATION.
  - (d) THE PROPOSED NEW SITE IS WITHIN THE SAME PLANNING AREA OF THE SITE AT WHICH THE EXISTING OHS SERVICE IS LOCATED AND WITHIN 5 MILES OF THE EXISTING OHS SERVICE LOCATION IF LOCATED IN A METROPOLITAN STATISTICAL AREA COUNTY, OR WITHIN 10 MILES OF THE EXISTING OHS SERVICE LOCATION IF LOCATED IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.
  - (e) THE EXISTING OHS SERVICE TO BE RELOCATED PERFORMED AT LEAST THE APPLICABLE MINIMUM NUMBER OF OPEN HEART SURGICAL CASES SET FORTH IN SECTION 8 AS OF THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT UNLESS THE OHS SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF THE ENTIRE HOSPITAL TO A NEW GEOGRAPHIC SITE.
  - (f) THE CARDIAC CATHETERIZATION AND OHS SERVICES SHALL CEASE OPERATION AT THE ORIGINAL SITE PRIOR TO BEGINNING OPERATION AT THE NEW SITE.
- Other technical edits.

The revisions to the CON Review Standards for Megavoltage Radiation Therapy (MRT) Services/Units received final approval by the CON Commission on June 13, 2019 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 12, 2019. The final language changes include the following:

- Updated the Department name throughout the document.

- Changed “dedicated stereotactic radiosurgery unit” to “dedicated stereotactic radiosurgery/stereotactic body radiation therapy (SRS/SBRT)” throughout the document.
- Section 10: Revised the weights and added additional factors and definitions for MR-guided real time tracking radiation w/o adaptive, MR-guided real time tracking radiation with adaptive, patient specific QA for IMRT, and patient specific QA for SRS/SBRT.
- Section 11(4): Reduced the maintenance volume for non-special MRT units from 8,000 ETVs annually to 4,000 ETVs annually.

The revisions to the CON Review Standards for Psychiatric Beds and Services received final approval by the CON Commission on March 21, 2019 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 May 24, 2019. The final language changes include the following:

- Revised the requirements of Section 8 “Requirements for approval of an applicant proposing to relocation existing licensed inpatient psychiatric beds” to include an exception where a child/adolescent service can be created, as follows in subsection (6):

  (6) The relocation of beds under this section shall not result in initiation of a new adult or child/adolescent service EXCEPT FOR AN EXISTING ADULT INPATIENT PSYCHIATRIC SERVICE REQUESTING TO INITIATE A CHILD/ADOLESCENT INPATIENT PSYCHIATRIC SERVICE IN AN OVERBEDDED CHILD/ADOLESCENT PLANNING AREA PURSUANT TO SECTION 9(11).
- Added new language in Section 9 “Requirements for approval to increase beds” with a new subsection 11 as follows:

- (11) AN APPLICANT PROPOSING TO INITIATE A NEW CHILD/ADOLESCENT PSYCHIATRIC SERVICE, AS THE RECEIVING LICENSED INPATIENT PSYCHIATRIC HOSPITAL OR UNIT UNDER SECTION 8(6), SHALL DEMONSTRATE THAT IT MEETS ALL OF THE REQUIREMENTS OF THIS SUBSECTION AND SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE BED NEED IF THE APPLICATION MEETS ALL OTHER APPLICABLE CON REVIEW STANDARDS AND AGREES AND ASSURES TO COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS.
  (a) THE APPROVAL OF THE PROPOSED NEW INPATIENT PSYCHIATRIC BEDS SHALL NOT RESULT IN AN INCREASE IN THE NUMBER OF LICENSED INPATIENT PSYCHIATRIC BEDS IN THE PLANNING AREA.
  (b) THE APPLICANT MEETS THE REQUIREMENTS OF SUBSECTIONS (4), (5), AND (6) ABOVE.
  (c) THE APPLICANT IS REQUESTING A MINIMUM OF 10 CHILD/ADOLSCENT PSYCHIATRIC BEDS TO A MAXIMUM OF 20 BEDS.
  (d) THE APPLICANT:
  (i) IS RELATED THROUGH COMMON OWNERSHIP, IN WHOLE OR IN PART, OR THROUGH COMMON CONTROL, WITH AN ACUTE-CARE HOSPITAL THAT HAS AN EMERGENCY DEPARTMENT THAT PROVIDES 24-HOUR EMERGENCY CARE SERVICES AND WHERE CHILD/ADOLESCENT PATIENTS WITH A PSYCHIATRIC AND/OR DEVELOPMENTAL DISABILITY DIAGNOSIS PRESENT AT AN AVERAGE OF AT LEAST 100 VISITS PER YEAR FOR EACH OF THE THREE MOST RECENT YEARS IN WHICH THERE IS DATA VERIFIABLE BY THE DEPARTMENT; AND
  (ii) HAS AN AGREEMENT WITH THE ACUTE-CARE HOSPITAL TO GIVE PRIMARY CONSIDERATION FOR ADMISSION OF CHILD/ADOLESCENT PATIENTS

FROM THE ACUTE-CARE HOSPITAL'S EMERGENCY DEPARTMENT IN NEED OF AN INPATIENT PSYCHIATRIC HOSPITAL ADMISSION.
(iii) HAS A COLLABORATIVE AGREEMENT WITH AN EXISTING CHILD/ADOLESCENT PSYCHIATRIC HOSPITAL OR UNIT FOR CONSULTATION AND SUPPORTIVE SERVICES WITH A PROPOSED TERM OF NOT LESS THAN TWELVE MONTHS AFTER IMPLEMENTATION.
(e) THE PROPOSED SITE FOR THE NEW CHILD/ADOLESCENT BEDS HAS NOT PREVIOUSLY BEEN APPROVED FOR BEDS UNDER THIS SUB-SECTION.
(f) THE PROPOSED PROJECT TO ADD NEW CHILD ADOLESCENT PSYCHIATRIC BEDS, UNDER THIS SUBSECTION, SHALL CONSTITUTE A CHANGE IN BED CAPACITY UNDER SECTION 1(2) OF THESE STANDARDS.
(g) APPLICANTS PROPOSING TO ADD NEW CHILD/ADOLESCENT PSYCHIATRIC BEDS UNDER THIS SUBSECTION SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW.

The following review standards were reviewed with an anticipated completion in FY2020:

Immune Effector Cell Therapy (IECT) Services: Proposed action was taken by the Commission at its June 20, 2019 meeting. The standards were submitted to the joint legislative committee (JLC) and a Public Hearing was held. The Commission took final action at its September 19, 2019 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period.

Psychiatric Beds and Services: Proposed action was taken by the Commission at its June 20, 2019 meeting. The standards were submitted to the joint legislative committee (JLC) and a Public Hearing was held. The Commission took final action at its September 19, 2019 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period.

Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services: Proposed action was taken by the Commission at its June 20, 2019 meeting. The standards were submitted to the joint legislative committee (JLC) and a Public Hearing was held. The Commission took final action at its September 19, 2019 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period.

Computed Tomography (CT) Scanner Services is being reviewed by an informal workgroup.

Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services is being reviewed by a standard advisory committee (SAC).

Nursing Home and Hospital Long-Term-Care Unit (HLTCU) Beds is being reviewed by a standard advisory committee (SAC).

APPENDIX I - CERTIFICATE OF NEED COMMISSION

James B. Falahee, Jr., JD, CON Commission Chairperson
Thomas Mittlebrun, III, Vice-Chairperson
Denise Brooks-Williams
J. Lindsey Dood
Tressa Gardner, DO
Debra Guido-Allen, RN
Robert L. Hughes
Melanie Lalonde
Amy McKenzie, MD
Melissa Oca, MD
Stewart Wang

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

DRAFT Certificate of Need (CON) Commission Work Plan

Attachment N

	2019						2020					
	July	August	September	October	November	December	January	February	March	April	May	June
Commission Meetings			Meeting			Meeting	Special Meeting		Meeting			Meeting
Cardiac Catheterization Services				Public Comment Period			Discussion/ Report					
Computed Tomography (CT) Scanner Services		CT Workgroup Mtg.	Interim Report to Commission	CT Workgroup Mtg.	CT Workgroup Mtg.	Interim Report to Commission	CT Workgroup Mtg.	CT Workgroup Mtg.	Report/Draft Language Presented/ Potential Proposed Action	Public Hearing		Report/ Final Action
Hospital Beds			Discussion of LAAs	Public Comment Period		Report/ Discussion of LAAs	Discussion/ Report					
Megavoltage Radiation Therapy (MRT) Services/Units				Public Comment Period			Discussion/ Report					
Neonatal Intensive Care Services/Beds (NICU)	SAC Nomination & Selection Period					NICU Workgroup Mtg.	NICU Workgroup Mtg.	NICU Workgroup Mtg.	NICU Workgroup Mtg.	NICU Workgroup Mtg.	NICU Workgroup Mtg.	Report/Draft Language Presented/ Potential Proposed Action
Nursing Home and HLTCU Beds and Addendum (NH-HLTCU)	SAC Nomination & Selection Period					NH-HLTCU SAC Mtg.	NH-HLTCU SAC Mtg.	NH-HLTCU SAC Mtg.	NH-HLTCU SAC Mtg.	NH-HLTCU SAC Mtg.	NH-HLTCU SAC Mtg.	NH-HLTCU SAC Mtg.
Open Heart Surgery (OHS) Services				Public Comment Period			Discussion/ Report					
Positron Emission Tomography (PET) Scanner Services				Public Comment Period			Discussion/ Report					
Surgical Services				Public Comment Period			Discussion/ Report					
New Medical Technology Standing Committee	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring

For Approval January 30, 2020.

Attachment N

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

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	June 2, 2014	2022
Bone Marrow Transplantation Services	September 29, 2014	2021
Cardiac Catheterization Services	December 26, 2018	2020
Computed Tomography (CT) Scanner Services	December 9, 2016	2019
Heart/Lung and Liver Transplantation Services	September 28, 2012	2021
Hospital Beds	November 28, 2018	2020
Magnetic Resonance Imaging (MRI) Services	October 21, 2016	2021
Megavoltage Radiation Therapy (MRT) Services/Units	September 12, 2019	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	December 26, 2018	2020
Positron Emission Tomography (PET) Scanner Services	September 14, 2015	2020
Psychiatric Beds and Services	November 12, 2019	2021
Surgical Services	November 17, 2017	2020
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	November 12, 2019	2022

*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.