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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 30<sup>th</sup> 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

- 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.
- 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.
- 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.

- 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.
- 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.

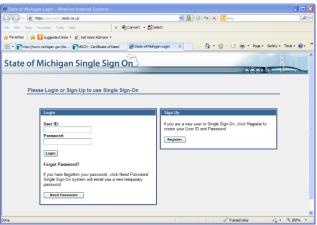
**Table 1** provides an overview of the number of LOIs received and processed in accordance with the above-referenced Rule.

| <u>TABLE 1</u><br>LETTERS OF INTENT RECEIVED AND PROCESSED WITHIN 15 DAYS<br>FY2015 - FY2019 |               |                          |                                  |                       |  |
|--|---------------|--------------------------|----------------------------------|-----------------------|--|
|  | LOIs Received | Processed within 15 Days | Percent Processed within 15 Days | Waivers<br>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.



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## Types of Certificate of Need Application Reviews

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

#### Nonsubstantive

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

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

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

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

# Substantive Individual

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

# Comparative

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

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

Figure 1 delineates services/beds subject to comparative review.

| FIGURE 1                     |   |  |  |  |  |
|------------------------------|---|--|--|--|--|
| Services/Beds S              | ubject 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.

| <u>TABLE 2</u><br>APPLICATIONS RECEIVED BY REVIEW TYPE<br>FY2015 - FY2019        |                                    |     |     |     |     |  |  |  |
|--|------------------------------------|-----|-----|-----|-----|--|--|--|
|  | FY2015 FY2016 FY2017 FY2018 FY2019 |     |     |     |     |  |  |  |
| Nonsubstantive*  | 194                                | 171 | 186 | 154 | 132 |  |  |  |
| Substantive Individual         129         148         89         142         72 |                                    |     |     |     |     |  |  |  |
| Comparative         0         0         0         6                              |                                    |     |     |     |     |  |  |  |
| TOTALS   | 323                                | 319 | 275 | 296 | 210 |  |  |  |

<sup>\*</sup> 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.

| <u>TABLE 3</u><br>APPLICATIONS RECEIVED AND PROCESSED WITHIN 15 DAYS<br>FY2015 - FY2019 |        |        |        |        |        |  |  |
|---|--------|--------|--------|--------|--------|--|--|
|   | FY2015 | FY2016 | FY2017 | FY2018 | FY2019 |  |  |
| Applications Received   | 326    | 320    | 275    | 296    | 210    |  |  |
| <b>Processed within 15 Days</b> 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.

| <u>TABLE 4</u><br>AVERAGE NUMBER OF DAYS IN REVIEW CYCLE BY REVIEW TYPE<br>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.

| <u>TABLE 5</u><br>EMERGENCY CON DECISIONS ISSUED<br>FY2015 - FY2019 |                                    |     |     |     |     |  |
|---|------------------------------------|-----|-----|-----|-----|--|
|   | FY2015 FY2016 FY2017 FY2018 FY2019 |     |     |     |     |  |
| Emergency CONs Issued 2 0* 0 0                                      |                                    |     |     |     |     |  |
| Percent Issued within 10 Working Days                               | 100%                               | N/A | N/A | N/A | N/A |  |

<sup>\*</sup>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.

| <u>TABLE 6</u><br>PROPOSED DECISIONS ISSUED<br>FY2015- FY2019 |        |                |        |                  |        |                |
|---|--------|----------------|--------|------------------|--------|----------------|
|   | Nor    | nsubstantive   | Substa | ntive 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.

| <u>TABLE 7</u><br>COMPARISON OF PROPOSED DECISIONS BY DECISION TYPE<br>FY2015- FY2019 |          |                           |             |                        |       |  |
|---|----------|---------------------------|-------------|------------------------|-------|--|
|   | Approved | Approved w/<br>Conditions | Disapproved | Percent<br>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.

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.

<sup>\*</sup> 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.

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

# FIGURE 2 FY 2019 FINAL DECISIONS ISSUED BY HEALTH SERVICE AREAS

| <u>TABLE 8</u><br>FINAL DECISIONS<br>ISSUED<br>FY2015- FY2019 |     |  |  |  |
|---|-----|--|--|--|
| FY2015  | 316 |  |  |  |
| FY2016  | 303 |  |  |  |
| FY2017  | 272 |  |  |  |
| FY2018  | 276 |  |  |  |
| FY2019  | 224 |  |  |  |



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.

| <u>TABLE 9</u><br>FINAL DECISIONS ACTIVITY CATEGORY<br>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.

| <u>TABLE 10</u><br>COMPARISON OF FINAL DECISIONS BY DECISION TYPE<br>FY2015 - FY2019 |                  |                          |                |                  |  |  |
|--|------------------|--------------------------|----------------|------------------|--|--|
|  | Approved         | Approved With Conditions | Disapproved    | Totals           |  |  |
|  | ۸                | lumber of Final Dec      | cisions        |                  |  |  |
| 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 Co         | sts            |                  |  |  |
| 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.

| <u>TABLE 11</u><br>CON ACTIVITY COMPARISON<br>FY2015 - FY2019 |                           |                                  |                        |                                  |  |  |  |
|---|---------------------------|----------------------------------|------------------------|----------------------------------|--|--|--|
|   | Number of<br>Applications | Difference from<br>Previous Year | Total Project<br>Costs | Difference from<br>Previous Year |  |  |  |
|   |                           | Letters of Intent Pro            | cessed                 |                                  |  |  |  |
| 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.

| <u>TABLE 12</u><br>AMENDMENTS RECEIVED AND DECISIONS ISSUED<br>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.

| <u>TABLE 13</u><br>COVERED CLINICAL SERVICES AND BEDS |                   |                        |              |                   |  |  |  |  |
|---|-------------------|------------------------|--------------|-------------------|--|--|--|--|
| FY2019  |                   |                        |              |                   |  |  |  |  |
| Covered Clinical Services/Beds                        | Existing<br>Sites | Existing<br>Units/Beds | New<br>Sites | New<br>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.

| <u>TABLE 14</u><br>FOLLOW UP AND COMPLIANCE ACTIONS<br>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         8 |     |     |     |     |     |  |  |
| 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.

| <u>FIGURE 3</u><br>CURRENT CON APPLICATION FEES |                                    |  |  |  |  |  |
|---|------------------------------------|--|--|--|--|--|
| Total Project Costs                             | <b>CON Application Fee</b>         |  |  |  |  |  |
| \$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              | \$3,000                            |  |  |  |  |  |
| Review, Acquisition or replacement of a         |                                    |  |  |  |  |  |
| licensed health facility with two or more       |                                    |  |  |  |  |  |
| covered clinical services.)                     |                                    |  |  |  |  |  |
| 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.

| <u>TABLE 15A</u><br>NUMBER OF CON APPLICATIONS BY FEE<br>FY2015 – FY2019 |                           |    |    |    |    |  |  |  |  |
|--|---------------------------|----|----|----|----|--|--|--|--|
| CON Fee FY 2015 FY2016 FY2017 FY2018 FY2019                              |                           |    |    |    |    |  |  |  |  |
| \$ O*  | 6 1 1 1                   |    |    |    |    |  |  |  |  |
| \$3,000  | \$3,000 146 166 95 123 76 |    |    |    |    |  |  |  |  |
| \$8,000 91 96 93 86 8  |                           |    |    |    |    |  |  |  |  |
| \$11,000   | 36                        | 27 | 42 | 30 | 23 |  |  |  |  |
| \$15,000 47 30 44 54 25  |                           |    |    |    |    |  |  |  |  |
| TOTAL  |                           |    |    |    |    |  |  |  |  |

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

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

| <u>TABLE 15B</u><br>NUMBER OF ADDITIONAL CON APPLICATION FEES<br>FY2015 – FY2019 |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|
| CON Fee Category   | 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                           |  |  |  |  |  |  |  |  |

<sup>\*</sup>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.

| <u>TABLE 16</u><br>CON PROGRAM |   |             |             |             |             |  |  |  |  |
|--------------------------------|---|-------------|-------------|-------------|-------------|--|--|--|--|
| CO                             | 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.

<sup>\*</sup> No fees are required for emergency CON and swing beds applications.

# **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.
  - (00) "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.
  - o (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:
  - O (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.
- O (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:

- o (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).
- (I) "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.
- O (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.
  - EACH PHYSICIAN CREDENTIALED BY A HOSPITAL TO PERFORM (d) 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.
- 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 MRguided 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
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For a list and contact information of the current CON Commissioners, please visit our web site at <a href="http://www.michigan.gov/con">http://www.michigan.gov/con</a>.