# *MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES*

# *CERTIFICATE OF NEED (CON) PROGRAM*

# *ANNUAL ACTIVITY REPORT*

***October 2016 through September 2017***
***(FY2017)***

MDHHS
Michigan Department of Health & Human Services
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## *EXECUTIVE SUMMARY*

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

### ***Administration***

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

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

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

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

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

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

## ***CON Required***

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

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

## ***CON Application Process***

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

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

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

## ***FY 2017 in Review***

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

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

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

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

## *HISTORICAL OVERVIEW OF MICHIGAN'S CERTIFICATE OF NEED PROGRAM*

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

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

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

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

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

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

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

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

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

## *ADMINISTRATION OF THE CERTIFICATE OF NEED PROGRAM*

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

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

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

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

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

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

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

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

## *CERTIFICATE OF NEED PROCESS*

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

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

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

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

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

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

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

## *LETTERS OF INTENT*

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

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

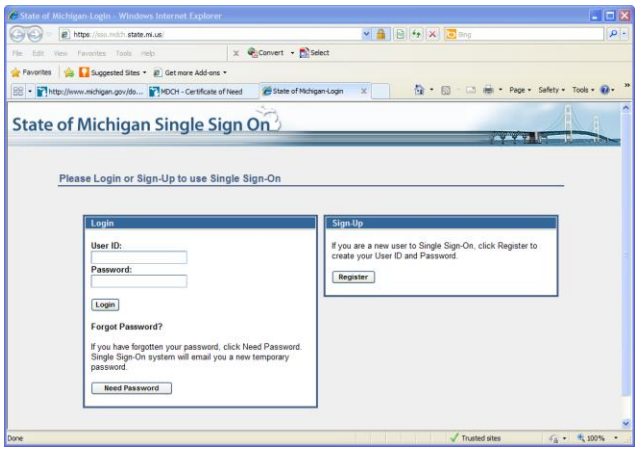
***TABLE 1***
*LETTERS OF INTENT RECEIVED AND PROCESSED WITHIN 15 DAYS*
*FY2013 - FY2017*

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

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

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

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

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## *TYPES OF CERTIFICATE OF NEED APPLICATION REVIEWS*

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

### ***Nonsubstantive***

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

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

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

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

***Substantive Individual***

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

***Comparative***

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

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

**Figure 1** delineates services/beds subject to comparative review.

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

*Note: See individual CON review standards for more information.*

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

***TABLE 2***
*APPLICATIONS RECEIVED BY REVIEW TYPE*
*FY2013 - FY2017*

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

* Includes 1 swing bed application.

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

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

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

*Note: Includes swing bed applications.*

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

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

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

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

## *EMERGENCY CERTIFICATES OF NEED*

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

***TABLE 5***
*EMERGENCY CON DECISIONS ISSUED*
*FY2013 - FY2017*

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

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

## *PROPOSED DECISIONS*

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

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

***TABLE 6***
*PROPOSED DECISIONS ISSUED*
*FY2013- FY2017*

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

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

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

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

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

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

## *FINAL DECISIONS*

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

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

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

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

***FIGURE 2***
***FY 2017 FINAL DECISIONS ISSUED BY HEALTH SERVICE AREAS***


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

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

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

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

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

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

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

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

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

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

*Note: Final decisions include emergency CON applications.*

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

## CERTIFICATE OF NEED ACTIVITY SUMMARY COMPARISON

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

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

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

## AMENDMENTS

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

- **Cost overruns -** The Rules allow the actual cost of a project to exceed the approved amount by 15 percent of the first $1 million and 10 percent of all costs over $1 million. Fluctuations in construction costs can cause projects to exceed approved amounts

- **Changes in the scope of a project -** An example is the addition of construction or renovation required by regulatory agencies to correct existing code violations that an applicant did not anticipate in planning the project or a change in covered clinical equipment.

- **Changes in financing -** Applicants may decide to pursue a financing alternative better than the financing that was approved in the CON.

- **Change in construction start date** – The Rules allow an Applicant to request an extension to start construction/renovation for an approved project.

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

***TABLE 12***
*AMENDMENTS RECEIVED AND DECISIONS ISSUED*
*FY2013 - FY2017*

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

## *NEW CERTIFICATE OF NEED CAPACITY*

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

***TABLE 13***
*COVERED CLINICAL SERVICES AND BEDS*
*FY2017*

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

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

## COMPLIANCE ACTIONS

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

| ***TABLE 14*** *FOLLOW UP AND COMPLIANCE ACTIONS FY2013 - FY2017* | | | | | |
|---|---|---|---|---|---|
| | **FY2013** | **FY2014** | **FY2015** | **FY2016** | **FY2017** |
| *Projects Requiring 1-yr Follow-up* | 340 | 350 | 251 | 314 | 303 |
| *Approved CONs Expired* | 127 | 97 | 95 | 51 | 78 |
| *Compliance Orders Issued* | 1 | 6 | 30 | 10 | 54 |

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

## ANALYSIS OF CERTIFICATE OF NEED PROGRAM FEES AND COSTS

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

| ***FIGURE 3A*** *PREVIOUS CON APPLICATION FEES* | |
|---|---|
| **Total Project Costs** | **CON Application Fee** |
| $0 to $500,000 | $1,500 |
| $500,001 to $4,000,000 | $5,500 |
| $4,000,001 and above | $8,500 |

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

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

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

| ***TABLE 15A*** *NUMBER OF CON APPLICATIONS BY FEE FY2013 - FY2014* | | |
|---|---|---|
| *CON Fee* | **FY2013** | **FY2014A** |
| *$ 0** | 6 | 0 |
| *$1,500* | 139 | 5 |
| *$5,500* | 97 | 8 |
| *$8,500* | 84 | 7 |
| *TOTAL* | 326 | 20 |

| ***TABLE 15B*** *NUMBER OF CON APPLICATIONS BY FEE FY2014 – FY2017* | | | | |
|---|---|---|---|---|
| *CON Fee* | **FY2014B** | **FY 2015** | **FY2016** | **FY2017** |
| *$ 0** | 3 | 6 | 1 | 1 |
| *$3,000* | 103 | 146 | 166 | 95 |
| *$8,000* | 70 | 91 | 96 | 93 |
| *$11,000* | 23 | 36 | 27 | 42 |
| *$15,000* | 16 | 47 | 30 | 44 |
| *TOTAL* | 215 | 326 | 320 | 275 |

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

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

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

| ***TABLE 15C*** *NUMBER OF ADDITIONAL CON APPLICATIONS FEES FY2014 – FY2017* | | | | |
|---|---|---|---|---|
| *CON Fee Category* | **FY2014B** | **FY 2015** | **FY2016** | **FY2017** |
| *Complex Project* | 8 | 3 | 0 | 9 |
| *Expedited Review* | 27 | 38 | 42 | 31 |
| *LOI Waiver** | 37 | 34 | 69 | 23 |
| *Amendment** | 32 | 44 | 54 | 56 |
| *Annual Survey (Facilities)* | 1,191 | 1,107 | 1,099 | 1,056 |

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

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

| ***TABLE 16*** *CON PROGRAM COST AND REVENUE SOURCES FOR FY2013– FY2017* | | | | | |
|---|---|---|---|---|---|
| | **FY2013** | **FY2014** | **FY2015** | **FY2016** | **FY2017** |
| *Program Cost* | $1,785,688 | $1,967,395 | $2,115,182 | $2,051,035 | $1,972,166 |
| *Fees/Funding* | $1,508,118 | $1,823,772 | $2,620,083 | $2,350,168 | $2,293,095 |
| *Fees % of Costs* | 84% | 93% | 100%+ | 100%+ | 100%+ |

*Source: MDHHS Budget and Finance Administration.*

## *CERTIFICATE OF NEED COMMISSION ACTIVITY*

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

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

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

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

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

- (iii) THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL; OR
- (iv) THE CT SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF AN ENTIRE HOSPITAL TO A NEW GEOGRAPHIC SITE AND HAS ONLY ONE (1) CT UNIT.

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

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

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

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

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

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

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

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

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

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

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

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

## *APPENDIX I - CERTIFICATE OF NEED COMMISSION*

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

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