MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) PROGRAM

ANNUAL ACTIVITY REPORT

October 2014 through September 2015
(FY2015)

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 27th report to the Commission and covers the period beginning October 1, 2014, through September 30, 2015 (FY 2015). 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 and Legislative Administration provides support for the CON Commission (Commission) and its Standards Advisory Committees (SAC). 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 2015, the Department has continued to make process improvements in both the Policy and Evaluation Sections. The Department successfully completed the performance audit of the CON Program by the Office of Auditor General (OAG) without any material findings and three reportable conditions. Since the completion of the audit the Policy and Evaluation Sections have developed policies and procedures to address the issues.

The Evaluation Section developed processes to implement the revised CON Review Standards for Cardiac Catheterization (CC) Services that includes elective percutaneous coronary intervention (PCI) services without on-site open heart surgery (OHS) services. The Section established new forms, review processes and accreditation criteria, and worked with both departmental and external subject matter experts to ensure proper review of elective PCI services. The Section also facilitated webinars and seminars to reach out to the providers regarding implementation plans for the CC Services standards. The Section completed enhancements to the CON Annual Survey tool for proper submission and validation of physician level data for CT, surgery and MRT services. The Section also established a statewide compliance schedule for covered services and streamlined procedures for follow-up.

The Policy Section assisted the Commission to make the necessary modifications to the CON Review standards to allow for elective PCI services without on-site OHS services and added specific quality measures to the standards; added inpatient rehabilitation facility (IRF) hospitals to the Hospital Beds standards; updated equivalent treatment visits (ETVs) and other parts of the Megavoltage Radiation Therapy (MRT) services standards to better reflect current practice; modified the comparative review requirements for Nursing Homes and Hospital Long-Term Care Unit (NH-HLTCU) Beds standards to better reflect current practice and assure quality; and updated the metropolitan statistical area, micropolitan statistical area, and rural counties in all impacted standards based on the 2010 Census data.

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 2015 in Review

In FY 2015, there were 435 Letters of Intent received resulting in 326 applications filed for CON review and approval, including three (3) emergency applications. In addition, the Department received 84 amendments to previously approved applications. In total, the Department approved 314 proposed projects resulting in approximately $2,317,168,916 of new capital expenditures into Michigan's healthcare system. The Department also surveyed 1,221 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.

The CON Commission also reviewed and revised 10 different CON review standards including: Cardiac Catheterization Services, Computed Tomography (CT) Services, Hospital Beds, Magnetic Resonance Imaging (MRI) Services, Megavoltage Radiation Therapy (MRT) Services/Units, 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, Positron Emission Tomography (PET) Scanner Services, Surgical Services, and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units.

This report is filed by the Department in accordance with MCL 333.2221(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.

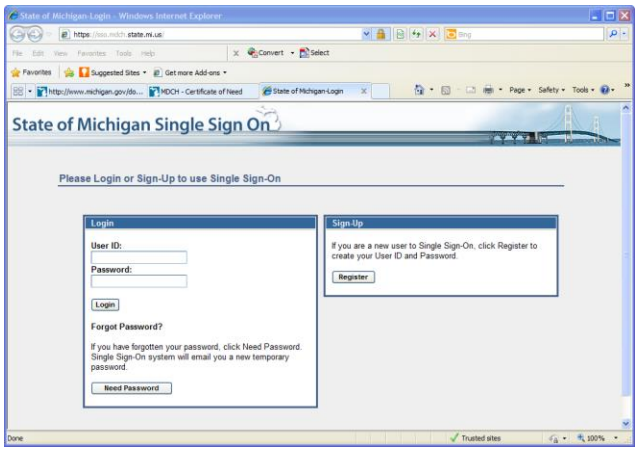
TABLE 1
LETTERS OF INTENT RECEIVED AND PROCESSED WITHIN 15 DAYS
FY2011 - FY2015

	LOIs Received	Processed within 15 Days	Percent Processed within 15 Days	Waivers Processed*
FY2011	441	438	99%	51
FY2012	422	422	100%	43
FY2013	440	438	99%	61
FY2014	333	332	99%	39
FY2015	435	434	99%	44

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

In FY 2015, LOIs were processed in a timely manner as required by Administrative Rule and available for public viewing on the online application system. The online system allows for faster processing of LOIs and subsequent applications by the Evaluation Section, as well as modifying these applications by applicants when needed.

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



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TYPES OF CERTIFICATE OF NEED APPLICATION REVIEWS

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

Nonsubstantive

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

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

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

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

Substantive Individual

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

Comparative

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

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

Figure 1 delineates services/beds subject to comparative review.

FIGURE 1 *Services/Beds Subject to Comparative Review in FY2015*	
Neonatal Intensive Care Unit	Nursing Home/HLTCU Beds
Hospital Beds	Nursing Home Beds for Special Population Groups
Psychiatric Beds	
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* *FY2011 - FY2015*					
	FY2011	**FY2012**	**FY2013**	**FY2014**	**FY2015**
Nonsubstantive*	166	160	161	117	194
Substantive Individual	122	135	152	114	129
Comparative	28	10	8	2	0
TOTALS	316	305	321	233	323

Note: Does not include three (3) emergency CON applications.

* Includes swing bed applications.

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

TABLE 3
APPLICATIONS RECEIVED AND PROCESSED WITHIN 15 DAYS
FY2011 - FY2015

	FY2011	FY2012	FY2013	FY2014	FY2015
Applications Received	318	305	326	235	326
Processed within 15 Days	315	290	326	235	324
Percent Processed within 15 Days	99%	95%	100%	100%	99%

Note: Includes emergency CON and 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
FY2011- FY2015

	FY2011	FY2012	FY2013	FY2014	FY2015
Nonsubstantive	31	41	38	40	42
Substantive Individual	110	114	117	117	112
Comparative	117	117	119	116	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
FY2011 - FY2015

	FY2011	FY2012	FY2013	FY2014	FY2015
Emergency CONs Issued	2	2	5	2	2*
Percent Issued within 10 Working Days	100%	100%	100%	100%	100%

*One emergency con application was withdrawn before a decision was 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
FY2011- FY2015

	Nonsubstantive		Substantive Individual		Comparative	
	Issued	Issued on Time	Issued	Issued on Time	Issued	Issued on Time
FY2011	180	100%	129	100%	34	100%
FY2012	155	100%	115	100%	3	100%
FY2013	147	100%	145	100%	9	100%
FY2014	119	100%	130	100%	6	100%
FY2015	195	100%	118	100%	0	N/A

Note: Table 6 does not include two (2) emergency proposed decisions.

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

TABLE 7
COMPARISON OF PROPOSED DECISIONS BY DECISION TYPE
FY2011- FY2015

	Approved	Approved w/ Conditions	Disapproved	Percent Disapproved	TOTAL
FY2011	298	30	15	6%	343
FY2012	244	19	10	4%	243
FY2013	261	35	10	3%	306
FY2014	222	28	7	3%	257
FY2015	261	53	1	0.3%	315

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 FY2011- FY2015*	
FY2011	323
FY2012	283
FY2013	309
FY2014	256
FY2015	316

FIGURE 2
FY 2015 FINAL DECISIONS ISSUED BY HEALTH SERVICE AREAS

Note: Figure 2 does not include 2 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 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 2014 the covered capital expenditure threshold was $3,160,000 and as of January 1, 2015, the covered capital expenditure threshold was increased to $3,197,500. The threshold is updated in January of every year.

TABLE 9 *FINAL DECISIONS ACTIVITY CATEGORY* *FY2011 - FY2015*					
Approved	**FY2011**	**FY2012**	**FY2013**	**FY2014**	**FY2015**
Acquire, Begin, or Replace a Health Facility	43	25	38	47	68
Change in Bed Capacity	54	57	52	46	34
Covered Clinical Services	212	188	241	191	214
Covered Capital Expenditures	78	55	44	47	33
Disapproved					
Acquire, Begin, or Replace a Health Facility	0	9	2	4	0
Change in Bed Capacity	0	12	5	5	1
Covered Clinical Services	1	2	0	0	1
Covered Capital Expenditures	0	10	3	5	1

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

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

TABLE 10 *COMPARISON OF FINAL DECISIONS BY DECISION TYPE* *FY2011 - FY2015*				
	Approved	**Approved With Conditions**	**Disapproved**	**Totals**
Number of Final Decisions				
FY2011	229	25	1	325
FY2012	245	24	14	283
FY2013	268	36	5	309
FY2014	223	28	5	256
FY2015	261	53	2	316
Total Project Costs				
FY2011	$ 4,237,317,904	$ 78,451,908	$ 96,000	$ 4,315,865,812
FY2012	$ 1,018,583,923	$ 61,902,640	$ 119,186,198	$ 1,199,672,761
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

Note: Final decisions include emergency CON applications.

In FY2015, two (2) CON applications received final decision of disapproval from the Department. These projects included an addition of nursing home beds to an existing facility and an emergency application for the temporary use of mobile MRI.

CERTIFICATE OF NEED ACTIVITY SUMMARY COMPARISON

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

TABLE 11 *CON ACTIVITY COMPARISON FY2011 - FY2015*				
	Number of Applications	**Difference from Previous Year**	**Total Project Costs**	**Difference from Previous Year**
Letters of Intent Processed				
FY2011	441	1%	$4,104,907,789	144%
FY2012	422	(4%)	$1,969,641,919	(52%)
FY2013	440	4%	$1,661,621,556	(16%)
FY2014	333	(24%)	$1,282,834,192	(23%)
FY2015	435	31%	$2,894,486,078	126%
Applications Submitted				
FY2011	318	5%	$3,896,990,034	159%
FY2012	307	(3%)	$1,351,924,859	(65%)
FY2013	326	6%	$1,539,877,626	14%
FY2014	235	(28%)	$ 904,601,983	(41%)
FY2015	326	39%	$2,526,962,926	179%
Final Decisions Issued				
FY2011	325	21%	$4,315,865,812	418%
FY2012	283	(13%)	$1,199,672,761	(72%)
FY2013	309	9%	$1,285,622,324	7%
FY2014	256	(17%)	$1,140,856,082	(11%)
FY2015	316	23%	$2,322,741,030	104%

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
FY2011 - FY2015

	FY2011	FY2012	FY2013	FY2014	FY2015
Amendments Received	83	68	73	63	84
Amendment Decisions Issued	76	66	84	60	88
Percent Issued within Required Time Frame	99%	100%	100%	99%	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 2015. One hundred and two (102) of the 314 CON approvals in FY 2015 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
FY2015

Covered Clinical Services/Beds	Existing Sites	Existing Units/Beds	New Sites	New Units/Beds
Air Ambulances	14	17	1	3
Cardiac Catheterization Services	68	219	1	5
Primary PCI *	14	N/A	1	N/A
Open Heart Surgical Services	34	N/A	0	N/A
Surgical Services	264	1,430	6	16
CT Scanners Services	435	526	34	35
MRI Services	324	242	5	6
PET Services	88	27	2	1
Lithotripsy Services	96	11	5	6
MRT Services	67	133	0	1
Transplant Services	8	N/A	0	N/A
Hospitals	183	26,440	1	0
NICU Services	22	632	0	0
SCN Services *	0	N/A	13	N/A
Extended Care Services Program (Swing Beds)	34	314	2	12
Nursing Homes/HLTCU	505	52,366	3	171
Psychiatric Hospitals/Units	63	2,525	0	20
Psychiatric Flex Beds *	3	28	0	16

Note: Table 13 does not account for facilities closed, services or equipment no longer operational, or beds delicensed and returned to the various bed pools. New sites include mobile host sites for CT, Lithotripsy, MRI and PET services.
** New service categories*

COMPLIANCE ACTIONS

Table 14 shows there were 350 projects requiring follow-up for FY 2015 based on the Department's Monthly Follow-up/Monitoring Report as shown below.

TABLE 14 *FOLLOW UP AND COMPLIANCE ACTIONS FY2011 - FY2015*					
	FY2011	**FY2012**	**FY2013**	**FY2014**	**FY2015**
Projects Requiring 1-yr Follow-up	341	386	340	350	251
Approved CONs Expired	80	69	127	97	95
Compliance Orders Issued	0	2	1	6	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 or remedies for non-compliance. The Department completed a statewide review of compliance of open heart and psychiatric 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
FY2011 - FY2014

CON Fee	FY2011	FY2012	FY2013	FY2014
$ 0*	2	2	6	0
$1,500	104	147	139	5
$5,500	101	96	97	8
$8,500	110	62	84	7
TOTAL	317	307	326	20

TABLE 15B
NUMBER OF CON APPLICATIONS BY FEE
FY2014 – FY2015

CON Fee	FY2014	FY 2015
$ 0*	3	6
$3,000	103	146
$8,000	70	91
$11,000	23	36
$15,000	16	47
TOTAL	215	326

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 – FY2015

CON Fee Category	FY2014	FY 2015
Complex Project	8	3
Expedited Review	27	38
LOI Waiver*	37	34
Amendment*	32	44
Annual Survey (Facilities)	1,191	1,099
TOTAL		

*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 FY2011– FY2015

	FY2011	FY2012	FY2013	FY2014	FY2015
Program Cost	$1,902,658	$1,802,307	$1,785,688	$1,967,395	$2,115,182
Fees/Funding	$1,715,588	$1,298,504	$1,508,118	$1,823,772	$2,620,083
Fees % of Costs	90%	72%	84%	93%	100%+

Source: MDCH Budget and Finance Administration.

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY2015, the CON Commission revised the review standards for Cardiac Catheterization Services, Computed Tomography (CT) Services, Hospital Beds, Magnetic Resonance Imaging (MRI) Services, Megavoltage Radiation Therapy (MRT) Services/Units, 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, Positron Emission Tomography (PET) Scanner Services, Surgical Services, and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units.

The revisions to the CON Review Standards for Cardiac Catheterization Services received final approval by the CON Commission on June 11, 2015 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 14, 2015. The final language changes include the following:

- Section 2: Definitions have been modified, and new definitions have been added as follows:
  - "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 cardiac catheterizations. This definition was updated.
  - “Elective percutaneous coronary intervention (PCI)” means a PCI procedure performed on a non-emergent basis. Definition added to allow for elective PCI without on-site open heart surgery.
  - “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 Updated on PCI Without On-Site Surgical Backup and published in circulation 2014, 129:2610-2626 and its update or further guideline changes. Definition added to allow for elective PCI without on-site open heart surgery.
  - “Primary percutaneous coronary intervention (PCI)” means a PCI performed on an acute myocardial infarction (AMI) patient with confirmed ST elevation or new left bundle branch block on an emergent basis. This definition was updated.
  - “Primary PCI service without on-site OHS” means performing primary PCI on an emergent basis in a hospital having a diagnostic cardiac catheterization service. Definition added for clarity.
  - "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. Procedures include PCI, PTCA, atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD device implantations, transcatheter valve, other structural heart disease procedures, PTCA with coronary stent implantation and left sided arrhythmia therapeutic procedures. The term does not include the intra coronary administration of drugs where that is the only therapeutic intervention. This definition was updated.
- Section 3(3): Revised consistent with current practice.
- Section 4: New section that provides the requirements to initiate primary PCI service without on-site OHS (previously included in Section 3) or elective PCI services without

on-site OHS services (new to standards). To be considered for an elective PCI service without on-site OHS services, the applicant shall have operated a primary PCI service for one year prior to the date of application. If the applicant was not approved as a primary PCI service prior to the effective date of the new standards, then, in addition, the applicant shall demonstrate that there is no PCI or OHS service within 60 radius miles or 60 minutes travel time from the proposed site.

- Section 7: Modified the language consistent with other CON review standards to clarify that any acquisition of a cardiac catheterization service, after the first acquisition, on or after February 27, 2012, must be meeting volume requirements to be acquired.
- Section 10(2): Revised consistent with current practice and national guidelines. Included a requirement for applicant hospitals providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective PCI services without on-site OHS service to participate with a data registry administered by the Department or its designee (currently BMC2) that monitors quality and risk adjusted outcomes.
- Section 10(4): Revised language for consistency with other changes in the standards as well as consistency with other CON review standards.
- Section 10(5): Updated the quality reporting criteria for primary and elective PCI for hospitals providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS services, or elective PCI services without on-site OHS service.
- Section 10(6) and (7): Added for administrative feasibility and consistent with other CON review standards.
- Section 12: Added requirements for documentation of projections for applicants proposing to initiate an elective PCI service without on-site OHS services.
- Appendix A: Updated the counties based on the 2010 Census data.
- Other technical edits.

The revisions to the CON Review Standards for CT Services received final approval by the CON Commission on September 25, 2014 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 22, 2014. The final language changes include the following:

- Section 24: Technical edit.
- Appendix B: Updated the counties based on the 2010 Census data.

The revisions to the CON Review Standards for Hospital Beds received final approval by the CON Commission on December 11, 2014 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 March 20, 2015. The final language changes include the following:

- Section 2: Definitions have been modified consistent with other CON review standards, and new definitions have been added as follows:
    - "Inpatient rehabilitation facility hospital" or "IRF hospital" means a hospital 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. Definition added to allow for IRF Hospitals the same considerations as LTAC Hospitals.
    - "Replace beds" means a change in the location of the licensed hospital, the replacement of a portion of the licensed beds at the same 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. The hospital beds will be in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, etc.) within the replacement zone. Definition modified to allow for a one-time replacement of beds to property separated by a road(s).

- Section 5: Modified consistent with other CON review standards.
- Section 6(2): Modified to allow for IRF Hospitals the same considerations as LTAC Hospitals.
- Section 7(2): Modified to allow for the one-time replacement of beds to property separated by a road(s). This includes the same additional language as added in the definition of "replace beds."
- Removal of Previous Section 10: Technical edit consistent with other CON Review Standards.
- Appendix B: Updated the counties based on the 2010 Census data.
- Other technical edits.

The revisions to the CON Review Standards for MRI Services received final approval by the CON Commission on September 25, 2014 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 22, 2014. The final language changes include the following:

- Previous Section 2(1)(hh), (ii) and (rr): Technical edit consistent with other CON Review Standards.
- Section 20: Technical edit.
- Appendix A: Updated the counties based on the 2010 Census data.

The revisions to the CON Review Standards for Hospital Beds received final approval by the CON Commission on March 18, 2014 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 June 2, 2014. The final language changes include the following:

- Section 4: Modified for the CD-9-CM to ICD-10-CM Code translation.
- Appendix E: Added new Appendix for the ICD-9-CM to ICD-10-CM Code translation.
- Other technical edits.

The revisions to the CON MRT Services/Units received final approval by the CON Commission on June 11, 2015 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 14, 2015. The final language changes include the following:

- Section 2: Definitions have been modified, moved, and/or deleted if no longer needed, and new definitions have been added as follows:
    - "Dedicated stereotactic radiosurgery unit" means an MRT unit for which more than 90 percent of cases will be treated with radiosurgery. The term wasn't previously defined.
    - "Megavoltage radiation therapy" or "MRT" means a clinical modality in which patients with cancer, other neoplasms, cerebrovascular system abnormalities, or certain benign conditions are treated with radiation which is delivered by a MRT unit. This definition was updated.
    - "Simulation" means the precise mock-up of a patient treatment with an apparatus

that uses a diagnostic x-ray tube, magnetic resonance imaging device, or computed tomography scanner, which is used in reproducing the two-dimensional or three-dimensional internal or external geometry of the patient, for use in treatment planning and delivery. This definition was updated.
    - "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following types of MRT units: (i) dedicated stereotactic radiosurgery unit, (ii) dedicated total body irradiator (TBI), or (iii) an OR-based IORT unit. This definition was updated.
    - "Treatment visit" means one patient encounter during which MRT is administered and billed. One treatment visit may involve one or more treatment ports or fields. Each separate encounter by the same patient at different times of the same day shall be counted as a separate treatment visit. Definition updated for clarification.
- Section 4(1)(a) and (d): Updated language to allow for replacement of a special purpose unit with a non-special purpose unit . The site at which a special purpose unit is replaced shall continue to operate a non-special purpose unit.
- Section 5(2)(a): Updated language to reflect that if expanding an existing MRT service with a special purpose MRT unit, that the applicant shall demonstrate that the existing and approved special purpose MRT units are averaging 1,000 ETVs in the most recent 12-month period in addition to the non-special MRT units averaging 8,000 ETVs in the most recent 12-month period.
- Section 6: Modified the language consistent with other CON review standards to clarify that any acquisition of an MRT service, after the first acquisition, on or after November 21, 2011, must be meeting volume requirements to be acquired.
- Section 10 Table 1 Equivalent Treatments: Updated to better reflect current practice.
- Section 11(2)(e)(ii): Revised as the American College of Radiology (ACR) and the American Society for Radiation Oncology (ASTRO) are no longer one organization, but two separate organizations.
- 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 25, 2014 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 22, 2014. The final language changes include the following:

- Section 14: Technical edit.
- Appendix A: Updated the counties based on the 2010 Census data.

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 December 11, 2014 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 March 20, 2015. The final language changes include the following:

- Section 1: Modified for consistency with other CON review standards.
- Section 2: Definitions have been modified, moved, and/or deleted if no longer needed, and a new definition has been added as follows:
    - “Applicant’s cash” has been revised to include contributions designated for the project from the landlord to reflect the investment by the lease holder.
    - “Proposed licensed site” means the physical location and address (or legal description of property) of the proposed project or within 250 yards of the physical

location and address (or legal description of property) and within the same planning area of the proposed project that will be authorized by license and will be listed on that licensee's certificate of licensure. This definition would allow for 250 yards of movement, if necessary, when a CON application has been approved, but the specific site cannot be used for new construction.

- Section 6(1)(a)(vi) and other applicable sections: Changed "outstanding" to "delinquent" to meet the intent and aid in administering this requirement.
- Section 6(1)(d)(ii) and 6(1)(d)(iii)(B): The Staffing/Bed Utilization Ratios Report is no longer available. The CON Annual Survey will now be used.
- Section 6(2)(c) and other applicable sections: Revised consistent with change under comparative review criteria in Section 10(7).
- Section 7(1)(b) and (c): Language revised consistent with the proposed new definition for "proposed licensed site."
- Section 7(3)(c)(i): Removed three mile radius language as it is no longer necessary. This was originally drafted for the pilot programs (new design model) in 2008, and all pilot programs are now CON approved.
- Section 8(1): Removed the restrictions of relocating no more than 50% of a nursing home's beds and the seven year restriction making it consistent with HLTCUs and added that relocation of beds shall not increase the number of rooms with three or more bed wards at the receiving facility
- Section 10(2): Updated to reduce redundancy and to simplify while maintaining the high consideration of Medicaid access.
- Old Section 10(3): Removed the points for Medicare participation within the most recent 12 months based on the modifications made to Section 10(2).
- New Section 10(3): Removed redundant special focus nursing home/HLTCU language.
- Section 10(4): Revised points. Qualifying projects that already participate or plan to participate in a culture change model will receive three points. They will receive an additional 5 points if the culture change model is a Department approved model.
- Old Section 10(6): Removed the requirement for sprinklers as this became Federal law in 2013.
- New Section 10(6): Revised to award points if there is climate control for the entire facility.
- Section 10(7): Revised language and points for facility design to create a more homelike environment for the resident while recognizing that there is still a need for semi-private rooms too.
- Old Section 10(11): Removed for redundancy as this is a requirement in the Administrative Rules.
- Section 10(10): Revised to award points if the entire facility will have no more than double occupancy rooms at completion of the project to help with improved quality of care.
- Section 10(11): Points revised to balance the points of comparative review based on the relevance of care to the resident.
- Section 10(12): Revised to reflect technology Innovations to better reflect on changes in healthcare, i.e. wireless nurse call/paging system for the proposed project; wireless internet with resident access to related equipment/device in entire facility; integrated electronic medical records system for the entire facility; a backup generator for the proposed project.
- Section 10(13): Added points if the proposed project includes bariatric rooms to ensure access for the bariatric resident.
- Section 11: Divided requirements into distinct groups consistent with other standards: quality assurance, access to care, and monitoring and reporting.
    - Under subsection (1), added clarifying language that an applicant approved

pursuant to Section 10 will be held accountable for complying with the requirements agreed to in the awarding of beds for the approved project.
    - Under new subsection (3), added access to care requirements consistent with other CON review standards.
- Other technical edits.

The revisions to the CON Review Standards for PET Scanner Services received final approval by the CON Commission on June 11, 2015 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 14, 2015. The final language changes include the following:

- Section 6(1) and (2): Updated acquisition language for clarity consistent with other CON review standard.
- Section 11(4)(a): Technical edit.
- Section 19: Technical edit.
- Appendix C: Updated the counties based on the 2010 Census data.

The revisions to the CON Review Standards for UESWL Services/Units received final approval by the CON Commission on September 25, 2014 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 22, 2014. The final language changes include the following:

- Section 12: Technical edit.
- Appendix C: Updated the counties based on the 2010 Census data.

APPENDIX I - CERTIFICATE OF NEED COMMISSION

Marc D. Keshishian, MD, CON Commission Chairperson
Suresh Mukherji, MD, CON Commission Vice-Chairperson
Denise Brooks-Williams
Gail J. Clarkson, RN, NHA
Kathleen Cowling, DO
James B. Falahee, Jr., JD
Charles M. Gayney (Appointment expired and replaced by Thomas Mittlebrun, III)
Robert L. Hughes
Jessica A. Kochin
Gay L. Landstrom, RN
Thomas Mittlebrun, III (Replaced Charles M. Gayney)
Luis A. Tomatis, MD

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