MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) PROGRAM

ANNUAL ACTIVITY REPORT

October 2015 through September 2016
(FY2016)

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 28th report to the Commission and covers the period beginning October 1, 2015, through September 30, 2016 (FY 2016). 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 2016, the Department has continued to make process improvements in both the Policy and Evaluation Sections. The Department made substantial progress in revising specific areas of the CON administrative rules, which is now in its final phase of the rule making process.

The Evaluation Section has initiated a compliance pilot program to monitor the denial of treatment for inpatient psychiatric patients and collect information from the Prepaid Inpatient Health Plans (PIHP). This pilot program is part of the department's evaluation of the mental health services and related issues in order to propose policy changes to enhance access to care. The 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 applications for elective percutaneous coronary intervention (PCI) services without on-site open heart surgery (OHS) services under the newly established review standards, 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 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. (Note: With the exception of MRI, these changes will become effective in FY2017.)

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 2016 in Review

In FY 2016, there were 442 Letters of Intent received resulting in 320 applications filed for CON review and approval, including one (1) emergency application. In addition, the Department received 76 amendments to previously approved applications. In total, the Department approved 303 proposed projects resulting in approximately $1,314,654,311 of new capital expenditures into Michigan's healthcare system. The Department also surveyed 1,137 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 FY2016, the CON Commission revised the review standards for Magnetic Resonance Imaging (MRI) 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.

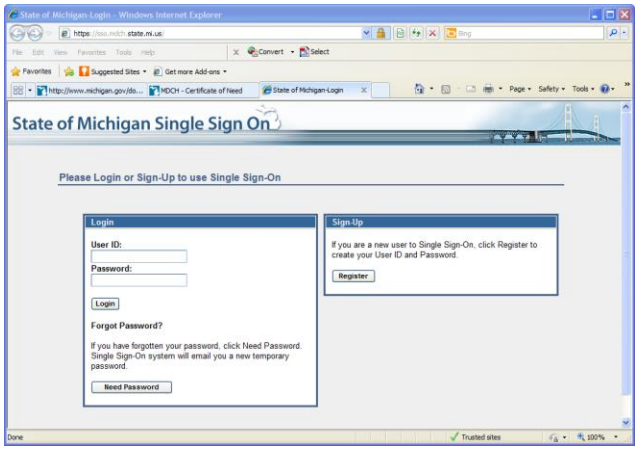
TABLE 1
LETTERS OF INTENT RECEIVED AND PROCESSED WITHIN 15 DAYS
FY2012 - FY2016

	LOIs Received	Processed within 15 Days	Percent Processed within 15 Days	Waivers Processed*
FY2012	422	422	100%	43
FY2013	440	438	99%	61
FY2014	333	332	99%	39
FY2015	435	434	99%	44
FY2016	442	439	99%	71

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

In FY 2016, 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 FY2016

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
FY2012 - FY2016

	FY2012	FY2013	FY2014	FY2015	FY2016
Nonsubstantive*	160	161	117	194	171
Substantive Individual	135	152	114	129	148
Comparative	10	8	2	0	0
TOTALS	305	321	233	323	319

Note: Does not include one (1) emergency CON application.

* 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
FY2012 - FY2016

	FY2012	FY2013	FY2014	FY2015	FY2016
Applications Received	305	326	235	326	320
Processed within 15 Days	290	326	235	324	318
Percent Processed within 15 Days	95%	100%	100%	99%	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
FY2012- FY2016

	FY2012	FY2013	FY2014	FY2015	FY2016
Nonsubstantive	41	38	40	42	38
Substantive Individual	114	117	117	112	104
Comparative	117	119	116	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
FY2012 - FY2016

	FY2012	FY2013	FY2014	FY2015	FY2016
Emergency CONs Issued	2	5	2	2*	0*
Percent Issued within 10 Working Days	100%	100%	100%	100%	N/A

*One 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
FY2012- FY2016

	Nonsubstantive		Substantive Individual		Comparative	
	Issued	Issued on Time	Issued	Issued on Time	Issued	Issued on Time
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
FY2016	169	100%	138	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
FY2012- FY2016

	Approved	Approved w/ Conditions	Disapproved	Percent Disapproved	TOTAL
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
FY2016	226	81	0	0%	307

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 FY2012- FY2016*	
FY2012	283
FY2013	309
FY2014	256
FY2015	316
FY2016	303

FIGURE 2
FY 2016 FINAL DECISIONS ISSUED BY HEALTH SERVICE AREAS

Note: Figure 2 does not include 3 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 2015 the covered capital expenditure threshold was $3,197,500 and as of January 1, 2016, the covered capital expenditure threshold was decreased to $3,180,000. The threshold is updated in January of every year.

TABLE 9 *FINAL DECISIONS ACTIVITY CATEGORY FY2012 - FY2016*					
Approved	**FY2012**	**FY2013**	**FY2014**	**FY2015**	**FY2016**
Acquire, Begin, or Replace a Health Facility	25	38	47	68	26
Change in Bed Capacity	57	52	46	34	42
Covered Clinical Services	188	241	191	214	240
Covered Capital Expenditures	55	44	47	33	49
Disapproved					
Acquire, Begin, or Replace a Health Facility	9	2	4	0	0
Change in Bed Capacity	12	5	5	1	0
Covered Clinical Services	2	0	0	1	0
Covered Capital Expenditures	10	3	5	1	0

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

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

TABLE 10 *COMPARISON OF FINAL DECISIONS BY DECISION TYPE FY2012 - FY2016*				
	Approved	**Approved With Conditions**	**Disapproved**	**Totals**
Number of Final Decisions				
FY2012	245	24	14	283
FY2013	268	36	5	309
FY2014	223	28	5	256
FY2015	261	53	2	316
FY2016	224	79	0	303
Total Project Costs				
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
FY2016	$ 1,000,284,403	$ 314,369,908	$ 0	$ 1,314,654,311

Note: Final decisions include emergency CON applications.

In FY2016, there were no CON applications that received a final decision of disapproval from the Department.

CERTIFICATE OF NEED ACTIVITY SUMMARY COMPARISON

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

TABLE 11 CON ACTIVITY COMPARISON FY2012 - FY2016				
	Number of Applications	**Difference from Previous Year**	**Total Project Costs**	**Difference from Previous Year**
Letters of Intent Processed				
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%
FY2016	442	2%	$1,527,863,597	(47%)
Applications Submitted				
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%
FY2016	320	(2%)	$1,235,892,460	(51%)
Final Decisions Issued				
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%
FY2016	303	(4%)	$1,314,654,311	(43%)

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
FY2012 - FY2016

	FY2012	FY2013	FY2014	FY2015	FY2016
Amendments Received	68	73	63	84	76
Amendment Decisions Issued	66	84	60	88	76
Percent Issued within Required Time Frame	100%	100%	99%	100%	97%

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 2016. One hundred and ten (110) of the 303 CON approvals in FY 2016 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
FY2016

Covered Clinical Services/Beds	Existing Sites	Existing Units/Beds	New Sites	New Units/Beds
Air Ambulances	15	20	1	1
Cardiac Catheterization Services	69	224	0	7
Primary PCI	15	N/A	0	N/A
Elective PCI*	0	N/A	10	N/A
Open Heart Surgical Services	34	N/A	0	N/A
Surgical Services	270	1,446	5	26
CT Scanners Services	469	561	42	46
MRI Services	329	248	5	3
PET Services	90	28	3	0
Lithotripsy Services	101	17	3	0
MRT Services	67	134	1	3
Transplant Services	8	N/A	0	N/A
Hospitals	184	26,440	1	62
NICU Services	22	632	0	0
SCN Services	13	N/A	1	N/A
Extended Care Services Program (Swing Beds)	36	326	1	6
Nursing Homes/HLTCU	508	52,537	0	148
Psychiatric Hospitals/Units	63	2,545	0	58
Psychiatric Flex Beds	3	44	0	0

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 category for elective PCI at a site that already offers primary PCI service.*

COMPLIANCE ACTIONS

Table 14 shows there were 303 projects requiring follow-up for FY 2016 based on the Department's Monthly Follow-up/Monitoring Report as shown below.

TABLE 14
FOLLOW UP AND COMPLIANCE ACTIONS
FY2012 - FY2016

	FY2012	FY2013	FY2014	FY2015	FY2016
Projects Requiring 1-yr Follow-up	386	340	350	251	303
Approved CONs Expired	69	127	97	95	51
Compliance Orders Issued	2	1	6	30	10

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 air ambulance. Other compliance orders issued included MRI, cardiac cath (PCI) and surgery 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 FY2012 - FY2014*			
CON Fee	**FY2012**	**FY2013**	**FY2014**
*$ 0**	2	6	0
$1,500	147	139	5
$5,500	96	97	8
$8,500	62	84	7
TOTAL	307	326	20

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

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 – FY2016*			
CON Fee Category	**FY2014**	**FY 2015**	**FY2016**
Complex Project	8	3	0
Expedited Review	27	38	42
*LOI Waiver**	37	34	69
*Amendment**	32	44	54
Annual Survey (Facilities)	1,191	1,107	1,099

*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 FY2012– FY2016*					
	FY2012	**FY2013**	**FY2014**	**FY2015**	**FY2016**
Program Cost	$1,802,307	$1,785,688	$1,967,395	$2,115,182	$2,051,035
Fees/Funding	$1,298,504	$1,508,118	$1,823,772	$2,620,083	$2,350,168
Fees % of Costs	72%	84%	93%	100%+	100%+

Source: MDHHS Budget and Finance Administration.

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY2016, the CON Commission revised the review standards for Magnetic Resonance Imaging (MRI) Services.

The revisions to the CON Review Standards for MRI Services received final approval by the CON Commission on March 16, 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 May 27, 2016. The final language changes include the following:

- Section 2: Definition has been modified as follows:
  - "Special needs patient" means a non-sedated patient, either pediatric or adult, with any of the following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD), developmental delay, malformation syndromes, hunter's syndrome, multi-system disorders, psychiatric disorders, implantable cardiac devices (ICDS), and other conditions that make the patient unable to comply with the positional requirements of the exam or is unable to comply with the motionless requirements and whose resulting movements result in non-diagnostic quality images therefore requiring the technologist to repeat the same sequence in an attempt to obtain a diagnostic quality image. Definition updated to better reflect practice and improve quality.
- Section 4(2): Definition has been modified as follows.
  - "Repair an existing MRI unit" means restoring the ability of the system to operate within the manufacturer's specifications by replacing or repairing the existing components or parts of the system, including the magnet, pursuant to the terms of an existing maintenance agreement with the manufacturer of the MRI unit that does not result in a change in the strength of the MRI unit. Definition updated for clarity.
- Section 4(3): Removed volume requirements for replacement of an MRI unit consistent with other CON review standards. Reduced regulation allows for facilities to more easily update equipment when it has surpassed its useful life.
- Section 4(4): Removed volume requirements for replacement of an existing mobile MRI host site to a new location. Reduced regulation allows for facilities to more easily replace an existing mobile MRI host site to a new location.
- Section 4(5): 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 MRI service and its unit(s) to a new location in certain situations that are unforeseen to the applicant.
  - (i) 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;
  - (ii) 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 MRI service and its unit(s) to a new site in certain situations that are unforeseen to the applicant:
  - (i) 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;
  - (ii) The ownership of the building where the site is located has changed within 24 months of the date of the service being operational; or
  - (iii) The MRI service being replaced is part of the replacement of an entire hospital to a new geographic site and has only one (1) MRI unit.
- Section 6: Modified the language consistent with other CON review standards to clarify

that any acquisition of an existing MRI unit from an existing MRI service must be meeting volume requirements to be acquired.

- Section 7: Modified the language consistent with other CON review standards to clarify that MRI adjusted procedures performed on a dedicated MRI unit cannot be used to demonstrate need or to satisfy MRI CON review standards requirements.
- Section 14(2)(d)(i)(D): Updated name of document.
- Section 18(4), (7), and (8): Revised for clarity.
- Other technical edits.

The following review standards were reviewed with an anticipated completion in FY2017:

Bone Marrow Transplantation (BMT) Services was reviewed by a standard advisory committee (SAC) and a recommendation was provided to the Commission at their June 15, 2016 meeting. Development of a needs based methodology is in process.

Computed Tomography (CT) Services: Proposed action was taken by the Commission at its June 15, 2016 meeting. The standards were submitted to the joint legislative committee (JLC) and a Public Hearing was held. The Commission took final action at its September 21, 2016 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period. Standards will become effective in FY2017.

MRI Services were reviewed a second time in FY2016 for recommendations regarding common ownership. Final action was taken by the Commission at its June 15, 2016 meeting. The standards were submitted to the joint legislative committee (JLC) and the Governor for the required 45-day review period. Standards will become effective in FY2017.

Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services: Proposed action was taken by the Commission at its June 15, 2016 meeting. The standards were submitted to the joint legislative committee (JLC) and a Public Hearing was held. The Commission took final action at its September 21, 2016 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period. Standards will become effective in FY2017.

Nursing Home and Hospital Long-Term Care Unit (NH-HLTCU) Beds and Addendum for Special Population Groups is being reviewed by an informal workgroup.

Psychiatric Beds and Services: Proposed action was taken by the Commission at its June 15, 2016 meeting. The standards were submitted to the joint legislative committee (JLC) and a Public Hearing was held. The Commission took final action at its September 21, 2016 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period. Standards will become effective in FY2017.

Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units: At its September 21, 2016 meeting, the Commission assigned the Department to draft language for the December 7, 2016 CON Commission meeting. Review of standards to be finalized in FY2017.

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
Debra Guido-Allen, RN
Robert L. Hughes
Jessica A. Kochin
Gay L. Landstrom, RN (Appointment expired and replaced by Debra Guido-Allen)
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 **http://www.michigan.gov/con**.