MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) PROGRAM

ANNUAL ACTIVITY REPORT

October 2012 through September 2013
(FY2013)

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EXECUTIVE SUMMARY

One of the Michigan Department of Community Health's (MDCH 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 25th report to the Commission and covers the period beginning October 1, 2012, through September 30, 2013 (FY 2013). 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 Health Planning and Access to Care Section 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 2013, the Department has continued to make process improvements in both the Policy and Evaluation Sections. The Evaluation Section worked with the Department's legislative liaison and Michigan Legislature to successfully enroll House Bill No. 4787 with new CON fees, and developed implementation plans for various types of CON fees. The Evaluation Section also made substantial progress in revising the CON administrative rules, which is now in its final phase of the rule making process. The Evaluation Section is making enhancements to the CON Annual Survey tool for collecting data as it relates to the project delivery requirements in various review standards; specifically, quality of care and access.

The Policy Section made improvements by converting Commission meetings to paperless, giving Commissioners and Departmental Staff the ability to access the most up-to-date information quickly and easily. The Policy and Evaluation Sections have developed a procedure to facilitate the departmental Program Specialist's recommendations directly into the policy development process.

These initiatives have greatly increased the availability of CON-related 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 Planning Administration
  - Appeal if applicant disagrees with the Proposed Decision issued
- Issuance of the Final Decision by the MDCH 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 2013 in Review

In FY 2013, there were 440 Letters of Intent received resulting in 326 applications filed for CON review and approval, including five (5) emergency applications. In addition, the Department received 73 amendments to previously approved applications. In total, the Department approved 304 proposed projects resulting in approximately $964,454,733 of new capital expenditures into Michigan’s healthcare system.

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 four (4) different CON review standards including Bone Marrow Transplantation (BMT) Services, Magnetic Resonance Imaging (MRI) Services, Megavoltage Radiation Therapy (MRT) Services/Units, and Psychiatric Beds and Services.

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 The goal of the program is to balance cost, quality, and access issues and ensure that only needed services are developed in Michigan. However, the program's ability to meet these goals was significantly diluted by the fact that most application denials were overturned in the courts. In order to address this, 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 program is now more predictable so that applicants can reasonably assess, before filing an application, whether a project will be approved. 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 for consideration of cost, quality, and access 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.

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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 FY2013.

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.

MDCH The Michigan Department of Community Health 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 Planning 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 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 Planning 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 of Community Health 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.

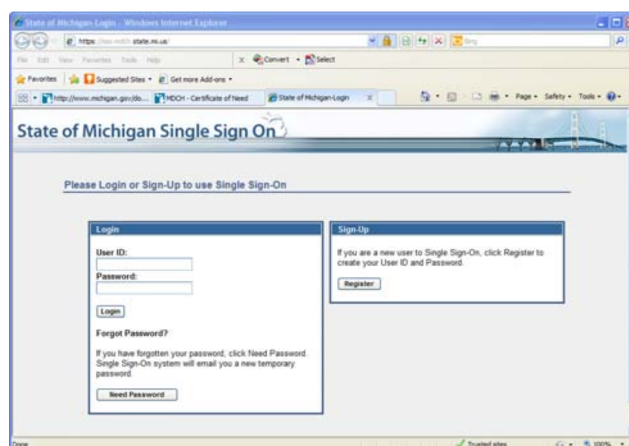
Table 1 provides an overview of the number of LOIs received and processed in accordance with the above-referenced Rule.

TABLE 1 *LETTERS OF INTENT RECEIVED AND PROCESSED WITHIN 15 DAYS* *FY2009 - FY2013*				
	LOIs Received	**Processed within 15 Days**	**Percent Processed within 15 Days**	**Waivers Processed***
FY2009	335	333	99%	31
FY2010	435	433	100%	61
FY2011	441	438	99%	51
FY2012	422	422	100%	43
FY2013	440	438	99%	61

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

In FY 2013, 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 all 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 FY2013*	
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* *FY2009 - FY2013*					
	FY2009	**FY2010**	**FY2011**	**FY2012**	**FY2013**
Nonsubstantive*	115	144	166	160	161
Substantive Individual	78	131	122	135	152
Comparative	26	22	28	10	8
TOTALS	219	297	316	305	321

Note: Does not include 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
FY2009 - FY2013

	FY2009	FY2010	FY2011	FY2012	FY2013
Applications Received	220	303	318	305	326
Processed within 15 Days	219	303	315	290	326
Percent Processed within 15 Days	100%	100%	99%	95%	100%

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
FY2009- FY2013

	FY2009	FY2010	FY2011	FY2012	FY2013
Nonsubstantive	38	37	31	41	38
Substantive Individual	113	113	110	114	117
Comparative	260*	153	117	117	119

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

* In FY 2009, the average days for comparative review applications increased substantially due to multiple revisions to the nursing homes review standards.

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
FY2009 - FY2013

	FY2009	FY2010	FY2011	FY2012	FY2013
Emergency CONs Issued	1	4	2	2	5
Percent Issued within 10 Working Days	100%	100%	100%	100%	100%

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.

TABLE 6
PROPOSED DECISIONS ISSUED
FY2009- FY2013

	Nonsubstantive		**Substantive Individual**		**Comparative**	
	Issued	Within 45 days	Issued	Within 120 days	Issued	Within 150 days
FY2009	130	100%	114	99%	20	90%
FY2010	123	99%	103	100%	17	100%
FY2011	180	100%	129	100%	34	100%
FY2012	155	100%	115	100%	3	100%
FY2013	147	100%	145	100%	9	100%

Note: Table 6 does not include emergency applications.

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

TABLE 7
COMPARISON OF PROPOSED DECISIONS BY DECISION TYPE
FY2009- FY2013

	Approved	**Approved w/ Conditions**	**Disapproved**	**Percent Disapproved**	**TOTAL**
FY2009	240	25	19	7%	284
FY2010	212	27	7	3%	246
FY2011	298	30	15	6%	343
FY2012	244	19	10	4%	243
FY2013	261	35	10	3%	306

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

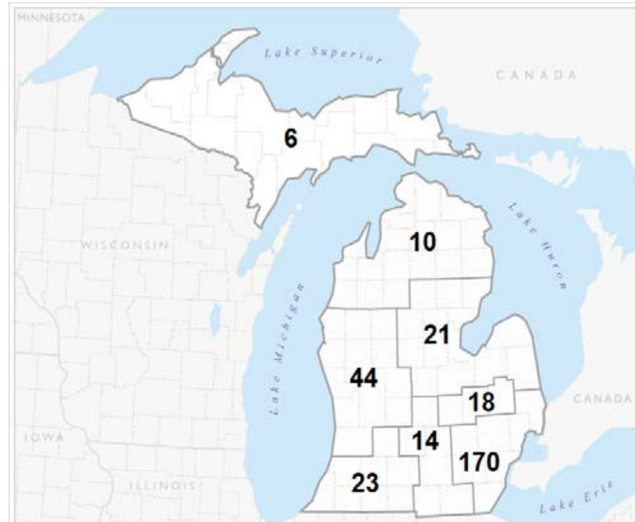
The Director issues a final decision on a CON application following either a proposed decision or the completion of a hearing, if requested, on a proposed decision. Pursuant to Section 22231(1) of the Public Health Code, the Director may issue a decision to approve an application, disapprove an application, 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 FY2009- FY2013*	
FY2009	271
FY2010	269
FY2011	323
FY2012	283
FY2013	309

FIGURE 2
FY 2013 FINAL DECISIONS ISSUED BY HEALTH SERVICE AREAS



Note: Figure 2 does not include 3 out-state decisions.

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

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

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

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

Covered Capital Expenditures
This category includes capital expenditure project in a clinical area of a licensed health facility that is equal to or above the threshold set forth in Part 222. Typical examples of covered capital expenditure projects include construction, renovation, or the addition of space to accommodate increases in patient treatment or care areas not already covered. As of January 1, 2013, the covered capital expenditure threshold was $3,097,500. The threshold is updated every January.

TABLE 9 *FINAL DECISIONS ACTIVITY CATEGORY* *FY2009 - FY2013*					
Approved	**FY2009**	**FY2010**	**FY2011**	**FY2012**	**FY2013**
Acquire, Begin, or Replace a Health Facility	49	44	43	25	38
Change in Bed Capacity	37	43	54	57	52
Covered Clinical Services	190	192	212	188	241
Covered Capital Expenditures	35	39	78	55	44
Disapproved					
Acquire, Begin, or Replace a Health Facility	1	5	0	9	2
Change in Bed Capacity	2	13	0	12	5
Covered Clinical Services	0	2	1	2	0
Covered Capital Expenditures	0	9	0	10	8

Note: Totals above may not match Final Decision totals because applications 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* *FY2009 - FY2013*				
	Approved	**Approved With Conditions**	**Disapproved**	**Totals**
Number of Final Decisions				
FY2009	240	27	3	271
FY2010	225	29	15	269
FY2011	229	25	1	325
FY2012	245	24	14	283
FY2013	268	36	5	309
Total Project Costs				
FY2009	$ 791,637,143	$ 317,924,357	$ 931,675	$ 1,110,493,175
FY2010	$ 712,964,774	$ 82,921,512	$ 36,912,278	$ 832,798,564
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

Note: Final decisions include emergency CON applications.

In FY2013, five (5) CON applications received final decision of disapproval from the Department. These projects included new nursing home beds and replacement hospital beds.

CERTIFICATE OF NEED ACTIVITY SUMMARY COMPARISON

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

TABLE 11 *CON ACTIVITY COMPARISON* *FY2009 - FY2013*				
	Number of Applications	**Difference from Previous Year**	**Total Project Costs**	**Difference from Previous Year**
Letters of Intent Processed				
FY2009	335	(36%)	$ 851,958,151	(72%)
FY2010	435	30%	$1,675,525,170	97%
FY2011	441	1%	$4,104,907,789	144%
FY2012	422	(4%)	$1,969,641,919	(52%)
FY2013	440	4%	$1,661,621,556	(16%)
Applications Submitted				
FY2009	219	(44%)	$ 604,642,399	(77%)
FY2010	303	38%	$1,503,768,132	149%
FY2011	318	5%	$3,896,990,034	159%
FY2012	307	(3%)	$1,351,924,859	(65%)
FY2013	326	6%	$1,539,877,626	14%
Final Decisions Issued				
FY2009	271	(23%)	$1,110,493,175	(69%)
FY2010	269	(1%)	$ 832,798,564	(25%)
FY2011	325	21%	$4,315,865,812	418%
FY2012	283	(13%)	$1,199,672,761	(72%)
FY2013	309	9%	$1,285,622,324	7%

Note: 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

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

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 provides a summary of amendment requests received by the Department and the time required to process and issue a decision.

TABLE 12 *AMENDMENTS RECEIVED AND DECISIONS ISSUED* *FY2009 - FY2013*	FY2009	FY2010	FY2011	FY2012	FY2013
Amendments Received	90	85	83	68	73
Amendment Decisions Issued	901	87	76	66	84
Percent Issued within Required Time Frame	93%	98%	99%	100%	100%

NEW CERTIFICATE OF NEED CAPACITY

Table 13 provides a comparison of existing covered services, equipment and facilities already operational to new capacity approved in FY 2013. One hundred and thirty-three (133) of the 304 CON approvals in FY 2013 were for new or additional capacity. The remaining approvals were for replacement equipment, renovations and other capital expenditures.

TABLE 13
COVERED CLINICAL SERVICES AND BEDS
FY2013

Covered Clinical Services/Beds	Existing Sites	Existing Units/Beds	New Sites	New Units/Beds
Air Ambulances	13	16	0	0
Cardiac Catheterization Services/ Primary PCI	68	212	0	2
Open Heart Surgical Services	34	N/A	0	0
Surgical Services	253	1,392	6	26
CT Scanners Services	353	445	40	38
MRI Services	293	234	17	6
PET Services	84	26	2	0
Lithotripsy Services	88	11	5	0
MRT Services	66	130	1	3
Transplant Services	8	N/A	0	N/A
Hospitals	176	26,400	1	40
NICU Services	22	632	0	0
Extended Care Services Program (Swing Beds)	33	309	0	0
Nursing Homes/HLTCU	483	50,798	17	1108
Psychiatric Hospitals/Units	62	2,375	0	58

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.

COMPLIANCE ACTIONS

Table 14 shows there were 340 projects requiring follow-up for FY 2013 based on the Department's Monthly Follow-up/Monitoring Report as shown below.

TABLE 14 *FOLLOW UP AND COMPLIANCE ACTIONS* *FY2009 - FY2013*					
	FY2009	**FY2010**	**FY2011**	**FY2012**	**FY2013**
Projects Requiring 1-yr Follow-up	379	326	341	386	340
Approved CONs Expired	155	217	80	69	127
Compliance Orders Issued	4	0	0	2	1

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.

ANALYSIS OF CERTIFICATE OF NEED PROGRAM FEES AND COSTS

Figure 3 shows the application fees that are based on total project costs. Section 20161(3) sets forth the fees to be collected for CON applications.

FIGURE 3 *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

Table 15 analyzes the number of applications by fee assessed.

TABLE 15 *NUMBER OF CON APPLICATIONS BY FEE* *FY2009 - FY2013*					
CON Fee	**FY2009**	**FY2010**	**FY2011**	**FY2012**	**FY2013**
*$ 0**	1	6	2	2	6
$1,500	103	113	104	147	139
$5,500	76	107	101	96	97
$8,500	39	77	110	62	84
TOTALS	219	303	317	307	326

Note: Table 15 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 16 provides information on CON program costs and source of funds.

TABLE 16 *CON PROGRAM* *COST AND REVENUE SOURCES FOR FY2009– FY2013*					
	FY2009	**FY2010**	**FY2011**	**FY2012**	**FY2013**
Program Cost	$1,871,395	$1,972,254	$1,902,658	$1,802,307	$1,785,688
Fees/Funding	$1,095,048	$1,423,451	$1,715,588	$1,298,504	$1,508,118
Fees % of Costs	59%	72%	90%	72%	84%

Source: MDCH Budget and Finance Administration.

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY2013, the CON Commission revised the review standards for Bone Marrow Transplantation (BMT) Services, Magnetic Resonance Imaging (MRI) Services, Megavoltage Radiation Therapy (MRT) Services/Units, and Psychiatric Beds and Services.

The revisions to the CON Review Standards for BMT Services received final approval by the CON Commission on December 13, 2012 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 22, 2013. The final language changes included the following:

- Section 1 - Modified for consistency with other CON review standards
- Section 2 - Definitions used only in certain section(s) were moved to the applicable section to make it easier for the reader to identify the defined terms, and other definitions were updated
    - "Acquisition of a BMT service" was moved to Section 4
    - "Initiate a BMT service" was moved to Section 3
- Section 6 - Updated Medicaid participation section consistent with other CON review standards
- Section 7 - Divided project delivery requirements into distinct groups (quality assurance, access to care, and monitoring and reporting)
- Appendix A - Health Service Areas moved to an Appendix consistent with other CON review standards
- Other technical changes.

The revisions to the CON Review Standards for MRI Services received final approval by the CON Commission on June 13, 2013 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 18, 2013. The final language changes included the following:

- Section 2 - Definitions were modified and/or moved to applicable section
- Section 4 - Clarified replace and upgrade definitions. Added a new definition for "repair an existing MRI unit." This is to allow components of an MRI unit to be repaired if under a service/maintenance agreement
    - Under subsection (3), added a one-time replacement of an existing MRI unit that is below 1 tesla with an MRI unit that is a 1 tesla or higher outside of volume requirements
    - Under subsection (4), added requirements to allow replacement of an existing mobile MRI host site to a new location similar to other CON standards
- Section 7 - Modified for consistency with other CON review standards in that the applicant agrees that the dedicated research MRI unit will be used primarily (70% or more of the procedures) for research purposes only
- Section 11 - Added requirements similar to intraoperative MRI (IMRI) to initiate, replace, or acquire an MRI simulator that will not be used solely for MRT treatment planning purposes
- Section 14 - Divided requirements into distinct groups consistent with other standards (quality assurance, access to care, and monitoring and reporting)
    - Under subsection (2)(d)(i)(D), revised to align with the "American College of Radiology (ACR) Practice Guideline for Performing and Interpreting Magnetic

    - Resonance Imaging (MRI)" language on MRI accreditation to ensure consistency with national standards
    - Under subsection (4)(b), added reporting requirement for MRI simulators approved under Section 11
- Section 15 - Increased the base value for functional MRI (fMRI) procedures, MRI-guided interventions, and cardiac MRI procedures, and added definitions for these procedures too
- Other technical edits.

The revisions to the CON Review Standards for MRT Services/Units received final approval by the CON Commission on March 28, 2013 and were forwarded to the Governor and Legislature. Neither the Governor nor the Legislature took a negative action within 45 days; therefore, the revisions became effective May 24, 2013. The final language changes included the following:

- Section 2 - Definitions were eliminated as they are no longer necessary, and a new definition was added
    - "Excess Equivalent Treatment Visits (ETVs)" means the number of ETVs performed by an existing MRT service in excess of 10,000 per MRT unit. The number of MRT units used to compute excess ETVs shall include both existing and approved but not yet operational MRT units. In the case of an MRT service that operates or has a valid CON to operate that has more than one MRT unit at the same site, the term means number of ETVs in excess of 10,000 multiplied by the number of MRT units at the same site. For example, if an MRT service operates, or has a valid CON to operate, two MRT units at the same site, the excess ETVs is the number that is in excess of 20,000 (10,000 x 2) ETVs.
- Old Section 3 - Eliminated as it's no longer needed due to other changes within the standard
- New Section 3 - Added language to allow for greater geographic access in Planning Area 8. An applicant will be exempt from projecting ETVs for initiation if it meets other specific criteria
- Section 9 - New methodology for projecting ETVs – projections will be based on the historical MRT volume of treating physicians. "Treating physician" is defined as the staff physician of the MRT service directing and providing the MRT treatment, not the referring physician. This models the language in the CON Review Standards for Computed Tomography (CT) Scanner Services
- Old sections 12 and 13 - Eliminated as they are no longer needed due to other changes within the standard
- New Section 11 - Added requirements to be accredited by the American College of Surgeons Commission on Cancer, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), or the Healthcare Facilities Accreditation Program (HFAP) and to be accredited by the American College of Radiology/American Society for Radiation Oncology (ACR/ASTRO) or the American College of Radiation Oncology (ACRO)
    - Under subsection (4)(b), MRT units approved pursuant to Section 3(3) in Planning Area 8 shall be operating at a minimum average volume of 5,500 ETVs annually.
- Old Appendices A and B - Eliminated as they are no longer needed
- Other technical changes.

The revisions to the CON Review Standards for Psychiatric Beds and Services received final approval by the CON Commission on December 13, 2012 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 22, 2013. The final language changes included the following:

- Section 1 - Modified for consistency with other CON review standards
- Section 2 - Definitions were modified and new definitions were added
  - "Flex bed" is defined as an existing adult psychiatric bed converted to a child/adolescent psychiatric bed in an existing child/adolescent psychiatric service to accommodate during peak periods and meet patient demand
  - "Relocate existing licensed inpatient psychiatric beds" means a change in the location of existing inpatient psychiatric beds from the existing licensed psychiatric hospital site to a different existing licensed psychiatric hospital site within the same planning area. This definition does not apply to projects involving replacement beds in a psychiatric hospital or unit governed by Section 7 of these standards
- Section 3 - The bed need methodology was run using the base year of 2010 and a planning year of 2015 (The bed need numbers were given immediate effect)
- Section 4 - Updated consistent with other standards and current practice. The bed need numbers will continue to be posted on the web site as part of the Psychiatric bed inventory, and the appendix in the standards will be eliminated
- Section 7 - Modified for consistency with other CON review standards
- Section 8 - Added requirements to allow for relocation of existing licensed inpatient psychiatric beds consistent with other standards
- Section 9 – Requirements for approval to increase beds were updated
  - Under subsection (2), defined calculation for average occupancy rate and modified the time period from 24 months to 12 months
  - Under subsection (3), modified the time period from 24 months to 12 months and added a calculation for high occupancy for facilities with flex beds
  - Added requirements under subsection (10) for a facility receiving licensed inpatient psychiatric beds under relocation (Section 8) consistent with other standards
- Section 10 - Added new section for flex beds. This will allow for a facility with an existing adult psychiatric service and an existing child/adolescent psychiatric service to convert adult psychiatric beds to child/adolescent psychiatric beds to accommodate during peak periods and meet patient demand
  - The existing adult psychiatric service/unit shall not become non-compliant with the minimum size requirements within section 6(4)
  - The applicant shall meet all applicable sections of the standards
  - The facility shall be in compliance and meet all design standards of the most recent Minimum Design Standards for Health Care Facilities in Michigan
  - The applicant shall convert the beds back to adult inpatient psychiatric beds if the bed has not been used as a flex bed serving a child/adolescent patient for a continuous 12-month period or if the CON application is withdrawn
- Section 14 - Divided requirements into distinct groups consistent with other standards (quality assurance, access to care, and monitoring and reporting)
  - Under subsection (4), added the calculation for average occupancy
- Updated/eliminated Appendices as applicable
- Other technical changes.

APPENDIX I - CERTIFICATE OF NEED COMMISSION

James B. Falahee, Jr., JD, CON Commission Chairperson
Marc D. Keshishian, MD, CON Commission Vice-Chairperson
Denise Brooks-Williams
Gail A. Clarkson
Kathleen Cowling, DO
Charles M. Gayney
Edward B. Goldman, JD (Appointment expired 4/9/13 and replaced by Denise Brooks-Williams)
Robert L. Hughes
Brian A. Klott
Gay L. Landstrom
Suresh Mukherji, MD
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**.