MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) PROGRAM

ANNUAL ACTIVITY REPORT

October 2013 through September 2014
(FY2014)

Michigan Department of Community Health

MDCH

Rick Snyder, Governor
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http://www.michigan.gov/con

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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 26th report to the Commission and covers the period beginning October 1, 2013, through September 30, 2014 (FY 2014). 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 Planning Administration provides support for the CON Commission (Commission) and it's 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 2014, the Department has continued to make process improvements in both the Policy and Evaluation Sections. The Evaluation Section developed processes to implement the new CON fees approved under House Bill No. 4787; the new CON fees include additional categories other than the base application fees, i.e., LOI waiver fee, amendment fee, complex review fee, expedited processing fee, and annual survey fee. The revised CON administrative rules were promulgated and became effective in February 2014. The Section completed 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 Section worked with the MDCH Medical Policy Unit to translate all of the ICD-9 codes to ICD-10 codes that appear in the CON review standards, application forms and annual survey tool. The Section also facilitated several webinars and seminars to reach out to the providers regarding implementation plans for the newly adopted Special Care Nursery CON standards.

The Policy Section assisted the Commission to make the necessary modifications to the CON Review standards to include International Disease Codes version 10 conversion charts to reflect the healthcare industry transition to this new diagnosis coding system; specific quality measures were added to standards; national safety standards for Special Newborn Nursing Services in the Neonatal Intensive Care Unit (NICU) Standards were added; revision to the Computed Tomography (CT) methodology to reflect current coding practices that will ensure better accuracy in determining need; and engaged in discussion to end the CON regulation of Air Ambulance Services due to federal law that limits the ability for states to limit the number of Air Ambulance services with need-based standards.

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 2014 in Review

In FY 2014, there were 333 Letters of Intent received resulting in 235 applications filed for CON review and approval, including two (2) emergency applications. In addition, the Department received 63 amendments to previously approved applications. In total, the Department approved 251 proposed projects resulting in approximately $1,101,326,083 of new capital expenditures into Michigan's healthcare system. The Department also surveyed 1,191 facilities and collected statistical data.

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

The CON Commission also reviewed and revised nine (9) different CON review standards including: Air Ambulance Services, Bone Marrow Transplantation (BMT) Services, Cardiac Catheterization Services, Computed Tomography (CT) Services, Hospital Beds, Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services, Open Heart Surgery (OHS) Services, Positron Emission Tomography (PET) Scanner Services, and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units

This report is filed by the Department in accordance with MCL 333.2221(f). The report presents information about the nature of these CON applications and decisions, as well as the Commission's actions during the reporting period. Several tables include benchmarks for timely processing of applications and issuing decisions as set forth in the CON Administrative Rules. Note that the data in the report represents some applications that were carried over from last fiscal year while others may be carried over into next fiscal year.

HISTORICAL OVERVIEW OF MICHIGAN'S CERTIFICATE OF NEED PROGRAM

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

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

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

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

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

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

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

Present The CON 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 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 FY2014.

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 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 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.

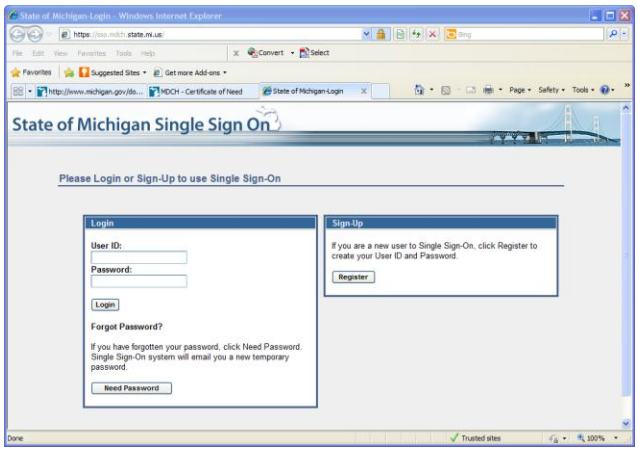
TABLE 1
LETTERS OF INTENT RECEIVED AND PROCESSED WITHIN 15 DAYS
FY2010 - FY2014

	LOIs Received	Processed within 15 Days	Percent Processed within 15 Days	Waivers Processed*
FY2010	435	433	100%	61
FY2011	441	438	99%	51
FY2012	422	422	100%	43
FY2013	440	438	99%	61
FY2014	333	332	99%	39

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

In FY 2014, 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 FY2014

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
FY2010 - FY2014

	FY2010	FY2011	FY2012	FY2013	FY2014
Nonsubstantive*	144	166	160	161	117
Substantive Individual	131	122	135	152	114
Comparative	22	28	10	8	2
TOTALS	297	316	305	321	233

Note: Does not include two (2) 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
FY2010 - FY2014

	FY2010	FY2011	FY2012	FY2013	FY2014
Applications Received	303	318	305	326	235
Processed within 15 Days	303	315	290	326	235
Percent Processed within 15 Days	100%	99%	95%	100%	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
FY2010- FY2014

	FY2010	FY2011	FY2012	FY2013	FY2014
Nonsubstantive	37	31	41	38	40
Substantive Individual	113	110	114	117	117
Comparative	153	117	117	119	116

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
FY2010 - FY2014

	FY2010	FY2011	FY2012	FY2013	FY2014
Emergency CONs Issued	4	2	2	5	2
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, or any requested extension(s) to the review cycle.

TABLE 6
PROPOSED DECISIONS ISSUED
FY2010- FY2014

	Nonsubstantive		Substantive Individual		Comparative	
	Issued	Issued on Time	Issued	Issued on Time	Issued	Issued on Time
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%
FY2014	119	100%	130	100%	6	100%

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

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

TABLE 7
COMPARISON OF PROPOSED DECISIONS BY DECISION TYPE
FY2010- FY2014

	Approved	Approved w/ Conditions	Disapproved	Percent Disapproved	TOTAL
FY2010	212	27	7	3%	246
FY2011	298	30	15	6%	343
FY2012	244	19	10	4%	243
FY2013	261	35	10	3%	306
FY2014	222	28	7	3%	257

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

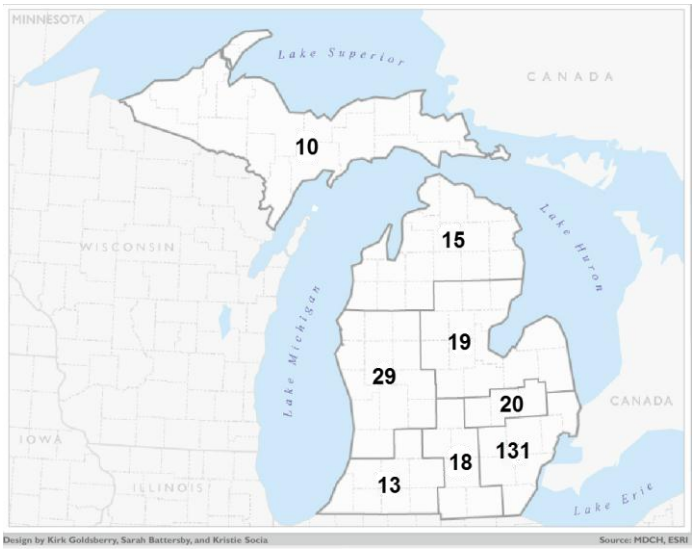
The Director issues a final decision on a CON application following either a proposed decision or the completion of a hearing, if requested, on a proposed decision. Pursuant to Section 22231(1) of the Public Health Code, the Director may issue a decision to approve an application, disapprove an application, 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 FY2010- FY2014*	
FY2010	269
FY2011	323
FY2012	283
FY2013	309
FY2014	256

FIGURE 2
FY 2014 FINAL DECISIONS ISSUED BY HEALTH SERVICE AREAS



Note: Figure 2 does not include 1 out-state decision.

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

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

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

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

Covered Capital Expenditures
This category includes capital expenditure 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 2013 the covered capital expenditure threshold was $3,097,500 and as of January 1, 2014, the covered capital expenditure threshold was increased to $3,160,000. The threshold is updated in January of every year.

TABLE 9 *FINAL DECISIONS ACTIVITY CATEGORY FY2010 - FY2014*					
Approved	**FY2010**	**FY2011**	**FY2012**	**FY2013**	**FY2014**
Acquire, Begin, or Replace a Health Facility	44	43	25	38	47
Change in Bed Capacity	43	54	57	52	46
Covered Clinical Services	192	212	188	241	191
Covered Capital Expenditures	39	78	55	44	47
Disapproved					
Acquire, Begin, or Replace a Health Facility	5	0	9	2	4
Change in Bed Capacity	13	0	12	5	5
Covered Clinical Services	2	1	2	0	0
Covered Capital Expenditures	9	0	10	3	5

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 FY2010 - FY2014*				
	Approved	**Approved With Conditions**	**Disapproved**	**Totals**
Number of Final Decisions				
FY2010	225	29	15	269
FY2011	229	25	1	325
FY2012	245	24	14	283
FY2013	268	36	5	309
FY2014	223	28	5	256
Total Project Costs				
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
FY2014	$ 904,329,614	$ 196,996,469	$ 39,529,999	$ 1,140,856,082

Note: Final decisions include emergency CON applications.

In FY2014, five (5) CON applications received final decision of disapproval from the Department. These projects included new nursing home beds.

CERTIFICATE OF NEED ACTIVITY SUMMARY COMPARISON

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

TABLE 11 CON ACTIVITY COMPARISON FY2010 - FY2014				
	Number of Applications	**Difference from Previous Year**	**Total Project Costs**	**Difference from Previous Year**
Letters of Intent Processed				
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%)
FY2014	333	(24%)	$1,282,834,192	(23%)
Applications Submitted				
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%
FY2014	235	(28%)	$ 904,601,983	(41%)
Final Decisions Issued				
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%
FY2014	256	(17%)	$1,140,856,082	(11%)

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

- **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
FY2010 - FY2014

	FY2010	FY2011	FY2012	FY2013	FY2014
Amendments Received	85	83	68	73	63
Amendment Decisions Issued	87	76	66	84	60
Percent Issued within Required Time Frame	98%	99%	100%	100%	99%

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 2014. One hundred and four (104) of the 251 CON approvals in FY 2014 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
FY2014

Covered Clinical Services/Beds	Existing Sites	Existing Units/Beds	New Sites	New Units/Beds
Air Ambulances	13	16	1	1
Cardiac Catheterization Services/ Primary PCI	68	214	0	5
Open Heart Surgical Services	34	N/A	0	N/A
Surgical Services	259	1,418	5	12
CT Scanners Services	393	483	42	43
MRI Services	310	240	14	2
PET Services	86	26	2	1
Lithotripsy Services	93	11	3	0
MRT Services	67	133	0	0
Transplant Services	8	N/A	0	N/A
Hospitals	177	26,440	6	0
NICU Services	22	632	0	0
Extended Care Services Program (Swing Beds)	33	309	1	5
Nursing Homes/HLTCU	500	51,906	5	460
Psychiatric Hospitals/Units	62	2,433	1	92

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.

COMPLIANCE ACTIONS

Table 14 shows there were 350 projects requiring follow-up for FY 2014 based on the Department's Monthly Follow-up/Monitoring Report as shown below.

TABLE 14
FOLLOW UP AND COMPLIANCE ACTIONS
FY2010 - FY2014

	FY2010	FY2011	FY2012	FY2013	FY2014
Projects Requiring 1-yr Follow-up	326	341	386	340	350
Approved CONs Expired	217	80	69	127	97
Compliance Orders Issued	0	0	2	1	6

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

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 from October 1, 2013 thru October 14, 2013.

FIGURE 3A
CON APPLICATION FEES 10/01/2013-10/14/2013

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
CON APPLICATION FEES 10/15/2013-09/30/2014

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 10/01/2013-10/14/2013* *FY2010 - FY2014*					
CON Fee	**FY2010**	**FY2011**	**FY2012**	**FY2013**	**FY2014**
*$ 0**	6	2	2	6	0
$1,500	113	104	147	139	5
$5,500	107	101	96	97	8
$8,500	77	110	62	84	7
TOTAL	303	317	307	326	20

TABLE 15B *NUMBER OF CON APPLICATIONS BY FEE 10/15/2013-09/30/2014* *FY2014*	
CON Fee	**FY2014**
*$ 0**	3
$3,000	103
$8,000	70
$11,000	23
$15,000	16
TOTAL	215

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 10/15/2013-09/30/2014* *FY2014*		
CON Fee Category	**FY2014**	**Total Amount**
Complex Project	8	$ 24,000
Expedited Review	27	$ 27,000
LOI Waiver	37	$ 18,500
*Amendment**	32	$ 16,000
Annual Survey	1,191 (Facilities)	$ 183,400
TOTAL		$ 268,900

*Note: Some amendments do not require an amendment 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 FY2010– FY2014*					
	FY2010	**FY2011**	**FY2012**	**FY2013**	**FY2014**
Program Cost	$1,972,254	$1,902,658	$1,802,307	$1,785,688	$1,967,395
Fees/Funding	$1,423,451	$1,715,588	$1,298,504	$1,508,118	$1,823,772
Fees % of Costs	72%	90%	72%	84%	93%

Source: MDCH Budget and Finance Administration.

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY2014, the CON Commission revised the review standards for Air Ambulance Services, Bone Marrow Transplantation (BMT) Services, Cardiac Catheterization Services, Computed Tomography (CT) Services, Hospital Beds, Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services, Open Heart Surgery (OHS) Services, Positron Emission Tomography (PET) Scanner Services, and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units.

The revisions to the CON Review Standards for Air Ambulance Services received final approval by the CON Commission on March 18, 2014, and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective June 2, 2014. The final language changes include the following:

- Section 1: Modified for consistency with other CON review standards. Relocation is a part of replacement.
- Section 2: Definitions have been moved to applicable sections if only used in that section. "Medicaid" definition has been removed as it is defined in Part 222 of the Public Health Code.
- Section 3: Removed "need" requirements for initiation.
- Section 4: Moved from Section 5 and removed "need" requirements for replacement. Added subsection (5) as a technical edit consistent with initiation and acquisition.
- Section 5: Moved from Section 4 and removed "need" requirements for expansion. Added subsection (4) as a technical edit consistent with initiation and acquisition.
- Section 6: Removed "need" requirements for acquisition.
- Section 8: Divided requirements into distinct groups consistent with other standards: quality assurance, access to care, and monitoring and reporting.
    - Under subsection (2), removed "need" based requirement for 275 patient transports annually.
- Section 9: "Need" based methodology removed.
- Other technical edits.

The revisions to the CON Review Standards for BMT Services received final approval by the CON Commission on June 12, 2014, and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective September 29, 2014. The final language changes include the following:

- Section 2(1)(e): "Cancer Hospital" is being redefined and "means a hospital that has been approved as a Comprehensive Cancer Center by the National Cancer Institute or operates a Comprehensive Cancer Center as an affiliate of a Michigan university that is designated as a Comprehensive Cancer Center by the National Cancer Institute."
- Section 4(1): Updated to reflect the removal of the PPS exemption requirement for acquisition by a cancer hospital.
- Section 4(2): Language added to allow for reacquisition of a BMT service by the current CON holder.
- Section 10(1): Technical edits.

The revisions to the CON Review Standards for Cardiac Catheterization Services received final approval by the CON Commission on March 18, 2014 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective June 2, 2014. The final language changes include the following:

- Section 2: Definition moved to applicable Appendix.
  - Subsection (1)(k): Modified for the ICD-9-CM to ICD-10-CM Code translation.
- Appendix B: Added new Appendix for the ICD-9-CM to ICD-10-CM Code translation.
- Other technical edits.

The revisions to the CON Review Standards for CT Services received final approval by the CON Commission on March 18, 2014, and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective June 2, 2014. The final language changes include the following:

- Section 1: Modified for consistency with other CON review standards. Relocation is a part of replacement.
- Section 2: Definitions have been modified, definitions moved to applicable sections if only used in that section, and new definitions have been added.
  - "Billable procedure" has been modified.
  - "Bundled body scan" is a new definition and is defined as "two or more body scans billed as one CT procedure.
  - "CT-angio hybrid unit" is a new definition and is defined as "an integrated system comprised of both CT and angiography equipment sited in the same room that is designed specifically for interventional radiology or cardiac procedures. The CT unit is a guidance mechanism and is intended to be used as an adjunct to the procedure. The CT unit shall not be used for diagnostic studies unless the patient is currently undergoing a CT-angio hybrid procedure and is in need of a secondary diagnostic study."
  - "Initiate a CT scanner service" has been modified as relocation is a part of replacement.
  - "Metropolitan statistical area county" is included in Appendix B.
  - "Micropolitan statistical area county" is included in Appendix B.
  - Relocation terms combined with replacement terms and/or section.
  - "Replace an existing CT scanner" modified to include relocation.
  - "Rural county" is included in Appendix B.
- Section 3: Under new subsection (4), added requirements to initiate CT scanner services as an existing host site on a different mobile CT scanner service consistent with other CON review standards.
- Section 4: Modified to include initiation of mobile dental CT scanner services.
  - Under new subsection (6), added requirements to initiate mobile dental CT scanner services as an existing host site on a different mobile dental CT scanner service consistent with other CON review standards.
- Section 6: Modified to include expansion of an existing mobile dental CT scanner service.
- Section 7:
  - Removed volume requirements for replacement of an existing fixed, mobile, or dedicated pediatric CT scanner.
  - New subsection (2) moved from old Section 9(1) and modified accordingly consistent with other CON review standards.

    - New subsection (3) moved from old Section 9(2) and modified accordingly consistent with other CON review standards.
- Section 8:
    - Removed volume requirements for replacement of an existing dental CT scanner or service.
    - New subsection (2) moved from old Section 10(1) and modified accordingly consistent with other CON review standards.
    - New subsection (3) moved from old Section 10(2) and modified accordingly consistent with other CON review standards.
- Section 9: Modified acquisition volume requirement of 7,500 CT equivalents for mobile to 3,500 CT equivalents consistent with required maintenance volumes.
- Section 10: Modified to include acquisition of an existing mobile dental CT scanner service or an existing mobile dental CT scanner.
- Section 11: Added requirements for a dedicated research fixed CT scanner consistent with other CON review standards.
- Section 12: Moved from Section 16.
- Section 13: Removed pilot language and made the requirements for approval of a hospital-based portable CT scanner for initiation, expansion, replacement, and acquisition a permanent part of the standards.
- Section 15: Added requirements for approval of a CT-angio hybrid unit for initiation, replacement, and acquisition.
- Section 17: Added additional requirements for approval of a mobile dental CT scanner service.
- Section 20: Divided requirements into distinct groups consistent with other standards: quality assurance, access to care, and monitoring and reporting.
    - Under subsection (4)(a), clarified language for maintenance volume requirements.
    - Under subsection (7), removed the reference to "pilot" program and updated language.
    - Under subsection (8), added project delivery requirements for CT-angio hybrid units.
- Section 22: Modified table for clarity and added "bundled body scan" with a conversion factor of 3.50 for adults and a conversion factor of 4.00 for pediatric/special needs patients.
- Section 23: Modified for clarity.
- Appendix A: Modified for consistency with other CON review standards.
- Other technical edits.

The revisions to the CON Review Standards for Hospital Beds received final approval by the CON Commission on March 18, 2014, and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective June 2, 2014. The final language changes include the following:

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

The revisions to the CON Review Standards for NICU and Special Newborn Nursing Services received final approval by the CON Commission on December 12, 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 March 3, 2014. The final language changes include the following:

- Section 1: Modified for consistency with other CON review standards.
- Section 2: Definitions have been modified, definitions moved to applicable sections if only used in that section, and a new definition has been added for "special care nursery services" or "SCN services."
- Section 5: Moved from previous Section 7.
- Section 6: Moved from previous Section 6.
- Section 7: Moved from previous Section 5.
- Section 9: Added requirements to initiate, acquire, or replace SCN services.
- Section 12: Divided requirements into distinct groups consistent with other standards: quality assurance, access to care, and monitoring and reporting.
    - Under subsection (3), added quality assurance requirements for SCN services.
    - Under subsection (5)(a)(i), added data reporting requirements for SCN services.
- Section 14: Added language to exempt SCN services from comparative review.
- Appendix B: Moved from previous Section 12.
- Other technical edits.

The revisions to the CON Review Standards for OHS Services received final approval by the CON Commission on September 17, 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 November 15, 2013. The final language changes include the following:

- Section 1: Modified for consistency with other CON review standards.
- Section 2: Definitions have been modified and a new definition has been added as follows:
    - "Hospital" means a health facility licensed under part 215 of the code.
- Section 7: Divided requirements into distinct groups consistent with other standards: quality assurance, access to care, and monitoring and reporting.
    - Under subsection (2)(b), reduced the minimum number of cases to be performed by the attending physician from 75 to 50 consistent with the national guidelines.
    - Under subsection (2)(c), added a requirement to participate with the Society of Thoracic Surgeons (STS) National Database and the Michigan Society of Thoracic and Cardiovascular Surgeons (MSTCVS) Quality Collaborative and Database or a designee of the Department that monitors quality and risk adjusted outcomes.
    - Under subsection (4)(a), for consistency, the data that is submitted to the CON Annual Survey will be the same data that is submitted to the STS Database for consistency. The maintenance volume is being reduced from 300 to 150 adult open heart surgical cases a year.
    - Under subsection (4)(d) and (e), added requirements to utilize and report the STS Composite Star Rating System for all procedures.
- Section 8: Modified for clarification.
- Section 9: Modified for clarification.
- Appendix A: Updated utilizing the 2010 Michigan Inpatient Data Base (MIDB).
- Appendix B: Updated utilizing the 2010 Michigan Inpatient Data Base (MIDB).
- Other technical edits.

A second set of revisions to the CON Review Standards for OHS Services received final approval by the CON Commission on March 18, 2014, and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective June 2, 2014. The final language changes include the following:

- Section 2: Definition moved to applicable Appendix.
  - Subsection (1)(m): Modified for the ICD-9-CM to ICD-10-CM Code translation.
- Section 8(3): Modified for the CD-9-CM to ICD-10-CM Code translation.
- Section 9(1)(a) and (e), (2)(a) and (c), and (3): Modified for the CD-9-CM to ICD-10-CM Code translation.
- Appendix A: Modified for the CD-9-CM to ICD-10-CM Code translation.
- Appendix B: Modified for the CD-9-CM to ICD-10-CM Code translation.
- Appendix C: Added new Appendix for the ICD-9-CM to ICD-10-CM Code translation.
- Appendix D: Added new Appendix for the ICD-9-CM to ICD-10-CM Code translation.
- Appendix E: Added new Appendix for the ICD-9-CM to ICD-10-CM Code translation.
- Other technical edits.

The revisions to the CON Review Standards for PET Scanner Services received final approval by the CON Commission on March 18, 2014, and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective June 2, 2014. The final language changes include the following:

- Section 12(4): Modified for the ICD-9-CM to ICD-10-CM Code translation.
- Appendix D: Added new Appendix for the ICD-9-CM to ICD-10-CM Code translation.
- Other technical edits.

The revisions to the CON Review Standards for UESWL Services/Units received final approval by the CON Commission on March 18, 2014, and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective June 2, 2014. The final language changes include the following:

- Section 1: Modified for consistency with other CON review standards.
- Section 2: Definitions have been moved to applicable sections if only used in that section.
- Section 3: Modified definition as relocation is a part of replacement.
- Section 4: Modified as relocation is a part of replacement.
- Section 5: Moved from Section 8.
- Section 7: Moved from Section 5.
- Section 9: Divided requirements into distinct groups consistent with other standards: quality assurance, access to care, and monitoring and reporting.
- Section 10: Modified for the ICD-9-CM to ICD-10-CM Code translation.
- Appendix A: Modified for the ICD-9-CM to ICD-10-CM Code translation.
  - Under subsection (1), updated the factor from .94 to 1.09.
  - Modified for clarity.
- Appendix B: Moved from Section 1.
- Appendix D: Added new Appendix for the ICD-9-CM to ICD-10-CM Code translation.
- Other technical edits.

APPENDIX I - CERTIFICATE OF NEED COMMISSION

James B. Falahee, Jr., JD, CON Commission Chairperson (10/1/13 – 3/18/14)
Marc D. Keshishian, MD, CON Commission Vice-Chairperson (10/1/13 – 3/18/14); Chairperson (Eff. 3/19/14)
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 (Resigned 11/14/13)
Jessica A. Kochin (Replaced Brian A. Klott)
Gay L. Landstrom
Suresh Mukherji, MD, Vice-Chairperson (Eff. 3/19/14)
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**.