MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) PROGRAM

ANNUAL ACTIVITY REPORT

October 2011 through September 2012
(FY2012)

Michigan Department of

MDCH

Rick Snyder, Governor
James K. Haveman, Director

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 24th report to the Commission and covers the period beginning October 1, 2011, through September 30, 2012 ("FY 2012"). 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 long term compliance with the terms and conditions of approvals.

During FY 2012, the Evaluation Section continued its work to move the program into the digital age. Staff continued to improve the online application and management information system (CON e-Serve). The first module was released in 2006. Today, the vast majority of letters of intent, CON applications, and amendments are filed online.

In this fiscal year we have continued to make enhancements to data quality validation criteria within the online MRI Validator, which verifies and stores the MRI utilization data. We have improved timeliness of data submissions through increased monitoring and achieved 100% submission rates. In addition, the application module, which processes new applications and verifies physician commitments, has been fully developed with all of the necessary reports.

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 health care 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:

a) Acquire an existing health facility or begin operation of a health facility.
b) Make a change in the bed capacity of a health facility.
c) Initiate, replace, or expand a covered clinical service.
d) 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 2012 in Review

In FY 2012, there were 422 letters of intent received resulting in 307 applications filed for CON review and approval, including two (2) emergency applications. In addition, the Department received 68 amendments to previously approved applications. In total, the Department approved 263 proposed projects resulting in approximately $1,080,486,563 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 eight (8) different CON review standards and deregulated one (1) review standard.

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 health-care 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 FY2012.

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 Standards Advisory Committees ("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 health-care 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 Bureau of Policy and Planning Administration.

Policy Section The Policy Section within the Bureau 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 Bureau 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") 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 — An applicant files on or before the designated application date an application with the Department and, if applicable, the regional review agency. 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 ("LOIs") 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 Letters of Intent received and processed in accordance with the above-referenced Rule.

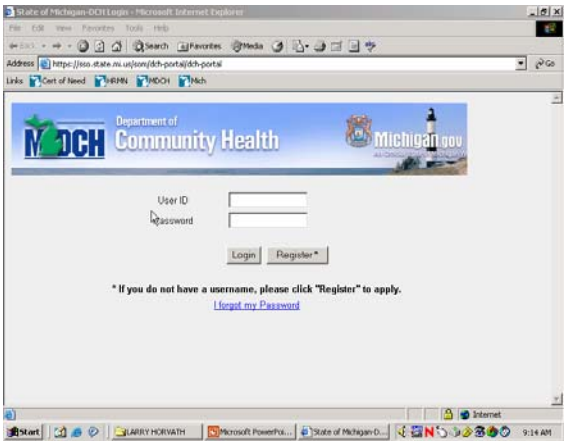
TABLE 1
LETTERS OF INTENT RECEIVED AND PROCESSED WITHIN 15 DAYS
FY2008 - FY2012

	LOIs Received	Processed within 15 Days	Percent Processed within 15 Days	Waivers Processed*
FY2008	521	517	99%	N/A
FY2009	335	333	99%	31
FY2010	435	435	100%	61
FY2011	441	438	99%	51
FY2012	422	422	100%	43

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

In FY 2012, all LOIs were processed in a timely manner as required by 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 Letters of Intent and more than 95% of all applications are submitted on-line.



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TYPES OF CERTIFICATE OF NEED APPLICATION REVIEWS

The Administrative Rules also establish three types of project reviews: nonsubstantive, substantive, and comparative. The Rules specify the time frames by which the Bureau 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 type 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; or
- Acquire or relocate an existing freestanding covered clinical service.

The Rules allow the Bureau 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 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 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 FY2011	
Neonatal Intensive Care Unit	Nursing Home Beds for Special Population Groups
Hospital Beds	Psychiatric Beds
Hospital Beds (HIV)	Transplantations
Nursing Home/HLTCU Beds	

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
FY2008 - FY2012

	FY2008	FY2009	FY2010	FY2011	FY2012
Nonsubstantive*	183	115	144	166	160
Substantive Individual	165	78	131	122	135
Comparative	37	26	22	28	10
TOTALS	385	219	297	316	305

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
FY2008 - FY2012

	FY2008	FY2009	FY2010	FY2011	FY2012
Applications Received	388	220	303	318	305
Processed within 15 Days	387	219	303	315	290
Percent Processed within 15 Days	100%	100%	100%	99%	95%

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
FY2008- FY2012

	FY2008	FY2009	FY2010	FY2011	FY2012
Nonsubstantive	40	38	37	31	41
Substantive Individual	116	113	113	110	114
Comparative	151	260*	153	117	117

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 attempts to issue emergency CON decision to the Director for final review and approval within 10 days from receipt of request.

TABLE 5
EMERGENCY CON DECISIONS ISSUED
FY2008 - FY2012

	FY2008	FY2009	FY2010	FY2011	FY2012
Emergency CONs Issued	3	1	4	2	2
Percent Issued within 10 Working Days	67%	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 to the applicant and the Department Director according to the time frames established in the Rules.

Table 6 shows the number of proposed decisions by type issued within the applicable time frames set forth in the Administrative Rules 325.9206 and 325.9207: 45 days for nonsubstantive, 120 days for substantive, and 150 days for comparative reviews.

TABLE 6
PROPOSED DECISIONS ISSUED
FY2008- FY2012

	Nonsubstantive		Substantive		Comparative	
	Issued	Within 45 days	Issued	Within 120 days	Issued	Within 150 days
FY2008	176	99%	145	99%	6	50%
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%

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

TABLE 7
COMPARISON OF PROPOSED DECISIONS BY DECISION TYPE
FY2008- FY2012

	Approved	Approved w/ Conditions	Disapproved	Percent Disapproved	TOTAL
FY2008	282	50	5	2%	337
FY2009	240	25	19	7%	284
FY2010	212	27	7	3%	246
FY2011	298	30	15	6%	343
FY2012	244	19	10	4%	273

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.

Figure 2
FY 2012 FINAL DECISIONS ISSUED BY HEALTH SERVICE AREAS

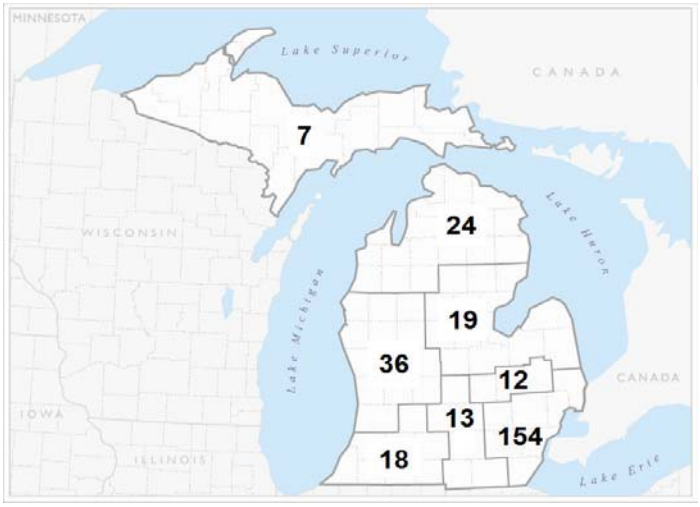

TABLE 8 FINAL DECISIONS ISSUED FY2008- FY2012	
FY2008	354
FY2009	271
FY2010	269
FY2011	323
FY2012	283

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, 2012, the covered capital expenditure threshold was $3,012,500. The threshold is updated every January.

TABLE 9 FINAL DECISIONS ACTIVITY CATEGORY FY2008 - FY2012					
Approved	**FY2008**	**FY2009**	**FY2010**	**FY2011**	**FY2012**
Acquire, Begin, or Replace a Health Facility	71	49	44	43	25
Change in Bed Capacity	20	37	43	54	57
Covered Clinical Services	228	190	192	212	188
Covered Capital Expenditures	30	35	39	78	55
Disapproved					
Acquire, Begin, or Replace a Health Facility	2	1	5	0	9
Change in Bed Capacity	1	2	13	0	12
Covered Clinical Services	2	0	2	1	2
Covered Capital Expenditures	1	0	9	0	10

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 FY2008 - FY2012				
	Approved	**Approved With Conditions**	**Disapproved**	**TOTALS**
Number of Final Decisions				
FY2008	291	59	4	354
FY2009	240	27	3	271
FY2010	225	29	15	269
FY2011	299	25	1	325
FY2012	245	24	14	283
Total Project Costs				
FY2008	$2,794,327,552	$719,560,182	$ 26,055.809	$3,539,943,543
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

Note: Final decisions include emergency CON applications.

CERTIFICATE OF NEED ACTIVITY SUMMARY COMPARISON

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

TABLE 11
CON ACTIVITY COMPARISON
FY2008 - FY2012

	Number of Applications	Difference from Previous Year	Total Project Costs	Difference from Previous Year
Letters of Intent Submitted				
FY2008	521	(10%)	$3,032,871,348	(9%)
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%)
Applications Submitted				
FY2008	388	21%	$2,577,833,078	(17%)
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%)
Final Decisions Issued				
FY2008	354	11%	$3,539,943,543	86%
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%)

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
FY2008 - FY2012

	FY2008	FY2009	FY2010	FY2011	FY2012
Amendments Received	68	90	85	83	68
Amendment Decisions Issued	71	91	87	76	66
Percent Issued within Required Time Frame	71%	93%	98%	99%	100%

NEW CERTIFICATE OF NEED CAPACITY

Table 13 provides a comparison of existing covered services, equipment and facilities already operational to new capacity approved in FY 2011. One hundred and ten (110) of the 269 CON approvals in FY 2012 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
FY2012

Covered Clinical Services/Beds	Existing Sites	Existing Units/Beds	New Sites	New Units/Beds
Air Ambulances	12	15	1	1
Cardiac Catheterization Services/ Primary PCI	68	205	0	7
Open Heart Surgical Services	34	N/A	0	N/A
Surgical Services	252	1,380	1	12
CT Scanners Services	327	421	26	24
MRI Services	283	229	10	5
PET Services	77	26	7	0
Lithotripsy Services	86	11	2	0
MRT Services	65	128	1	2
Transplant Services	7	N/A	1	N/A
Hospitals	176	26,376	0	24
NICU Services	22	627	0	5
Short-term Nursing (Swing Beds)	33	309	0	0
Nursing Homes/HLTCU	473	49,538	10	1260
Psychiatric Hospitals/Units	62	2,261	0	114

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

There were 386 projects requiring follow-up for FY 2012 based on the Department's Monthly Follow-up/Monitoring Report as shown in **Table 14.**

TABLE 14 FOLLOW UP AND COMPLIANCE ACTIONS FY2008 - FY2012					
	FY2008	**FY2009**	**FY2010**	**FY2011**	**FY2012**
Projects Requiring 1-yr Follow-up	471	379	326	341	386
Approved CONs Expired	88	155	217	80	69
Compliance Orders Issued	1	4	0	0	2

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. The fees are based on total project costs and are set forth in **Figure 3**.

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 FY2008 - FY2012					
CON Fee	**FY2008**	**FY2009**	**FY2010**	**FY2011**	**FY2012**
*$ 0**	4	1	6	2	2
$1,500	128	103	113	104	147
$5,500	151	76	107	101	96
$8,500	109	39	77	110	62
TOTALS	392	219	303	317	307

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 FY2008– FY2012					
	FY2008	**FY2009**	**FY2010**	**FY2011**	**FY2012**
Program Cost	$1,960,655	$1,871,395	$1,972,254	$1,902,658	$1,802,307
Fees/Funding	$1,742,926	$1,095,048	$1,423,451	$1,715,588	$1,298,504
Fees % of Costs	89%	59%	72%	90%	72%

Source: MDCH Budget and Finance Administration.

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY2012, the CON Commission revised the review standards for Cardiac Catheterization Services, Computed Tomography (CT) Scanner Services, Heart/Lung and Liver (HLL) Transplantation Services, Hospital Beds, Magnetic Resonance Imaging (MRI) Services, Megavoltage Radiation Therapy (MRT) Services/Units, Pancreas Transplantation Services, Positron Emission Tomography (PET) Scanner Services, and Surgical Services.

The revisions to the CON Review Standards for Cardiac Catheterization Services received final approval by the CON Commission on December 15, 2011 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 February 27, 2012. The final language changes include the following:

- Section 1: Modified for consistency with other CON review standards.
- Section 2: Definitions used only in certain section(s) have been moved to the applicable section to make it easier for the reader to identify the defined terms.
    - Eliminated definitions that are no longer needed.
    - Clarified definitions.
    - Modified definition for cardiac catheterization procedure to exclude the implantation of cardiac permanent pacemakers and implantable cardioverter defibrillators (ICD) devices that are performed in an interventional radiology laboratory or operating room.
    - Modified definition for therapeutic cardiac catheterization service to include transcatheter valves, other structural heart disease procedures, and left sided arrhythmia procedures.
- Section 3: Sections 3, 4, 5, 6, and 7 were combined as these sections related to the initiation of a CC service, and the section was modified for consistency with other CON review standards for initiation of CC services.
    - Subsection 4 was modified to reflect the SACs recommendation of the minimum 500 procedure equivalents to initiate, in which 400 must be within the category of CC procedures.
    - Projection procedures for initiation of primary percutaneous coronary intervention (PCI) decreased from 48 to 36.
    - Annual maintenance volume requirements have been moved to the project delivery requirements.
- Section 4: The replacement section will cover both the replacement of the laboratory and equipment as well as replacing the existing service to a new geographical site as part of replacing the entire hospital.
    - Replacement of a laboratory or equipment will no longer require the applicant to meet set volume requirements. Upgrades to existing CC services, without replacement of the laboratory or equipment will not require CON review/approval.
    - Clarified replacement definition as it applies to CC laboratories and relocation of CC service to a new site.
- Section 5: Eliminated the requirement to project procedure equivalents.
    - Modified the volume requirement for existing and approved laboratories to 1,400 procedure equivalents, and minimum threshold must be met in each applicable service category.
- Section 6: Added language for acquisition consistent with other CON review standards which includes the following:
    - Acquisition of CC services as part of the overall acquisition of a hospital.

    - Renewal of lease for angiography x-ray equipment without volume requirements.
- Section 7: Added language to define and outline requirements for a hybrid operating room/cardiac catheterization laboratory (OR/CCL).
- Section 8: Modified language consistent with other CON review standards on Medicaid participation requirement.
- Section 9: Divided requirements into distinct groups: quality assurance, access to care, monitoring and reporting, and specialized services. Annual volume requirements have been moved to the applicable project delivery requirements subsection.
- Section 10: Language under the previous Section 11(2) was deleted to allow for the counting of peripheral catheterizations under expansion. Further, due to elimination of volume requirements for replacement, this language is no longer necessary.
    - The procedures and weight equivalents were modified for simplification.
- Section 11: Modified the language to reflect the minimum projected volume requirement from 48 to 36 ST segment elevation AMI cases for primary PCI services.
- Other technical changes.

The revisions to the CON Review Standards for CT Services received final approval by the CON Commission on December 15, 2011 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 February 27, 2012. The final language changes include the following:

- Section 1: Modified the language consistent with recent changes in other CON review standards.
- Section 2(1) (b): Modified the definition "billable procedure" to read as follows: "'Billable procedure' means a CT procedure billed as a single unit under procedure codes in effect on December 31, 2010, and performed in Michigan."
- Section 2(1) (p): Added a definition for "excess CT equivalents."
- Section 2(1) (v): Added a definition for "health service area" or "HSA."
- Section 4(3): Removed minimum volume requirements for HSA 8 to encourage dental CT scanner service in the Upper Peninsula.
- Section 7(1) (d): Added a one-time exemption of having to meet the volume requirements for replacing an obsolete CT scanner.
- Section 13(3): Modified pilot language for hospital-based portable CT scanners. In addition to level I and level II trauma facilities, eligibility would be extended to those facilities that performed >100 craniotomies in the most recent 12-month period verifiable by the Department.
- Section 13(7): Renewed the pilot project to obtain sufficient data to fully evaluate the use of these scanners. Applications must be received on or before December 1, 2013, all provisions will expire on December 31, 2016, and be of no further force and effect unless the Commission makes them a permanent part of the CT scanner services standards.
- Section 19(5): Added language that allows portable CT scanners to be used in adult or pediatric intensive care units (ICU) by qualifying pilot program institutions and must be limited to brain scanning of those patients who are being treated in an ICU or for non-diagnostic, intraoperative guidance in an operating room. Also, added specific reporting requirements for those approved under the pilot language for hospital-based portable CT scanners: 1) number of adult studies (age>=18), 2) number of pediatric studies (age<18), 3) number of studies performed using a portable CT on the same patient while that patient is in an ICU, and 4) number of patients scanned on a portable CT that underwent subsequent scanning on a fixed CT within 12 hours of the portable CT scan.

- Section 22(4): Added language that only excess CT equivalents may be used for projections when initiating CT services.
- Section 24: Added HSAs to the standards.
- Other technical changes.

The revisions to the CON Review Standards for HLL Transplantation Services received final approval by the CON Commission on June 14, 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 September 28, 2012. The final language changes include the following:

- Section 1: Modified for consistency with other CON review standards.
- Section 2: Definitions used only in certain section(s) have been moved to the applicable section to make it easier for the reader to identify the defined terms, and other definitions have been updated. Specifically:
    - "Comparative group" - has been moved to Section 7.
    - "Initiate" or "implement" - has been moved to Section 3.
    - "Qualifying project" - has been moved to Section 7.
    - "Medicaid" – has been updated.
- Section 6: Moved Medicaid participation requirements to its own section consistent with other CON review standards.
- Section 8: Divided requirements into distinct groups: quality assurance, access to care, monitoring and reporting, and specialized services.
- 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 Hospital Beds received final approval by the CON Commission on June 14, 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 September 28, 2012. The final language changes include the following:

- Section 1: Modified for consistency with other CON review standards.
- Section 2: Definitions used only in certain section(s) have been moved to the applicable section to make it easier for the reader to identify the defined terms.
    - Eliminated definitions that are no longer needed.
    - Modified definitions.
    - Added new definitions:
        - "Adjusted patient days" is defined as it's used in various sections of the standards.
        - "Average adjusted occupancy rate" is defined as it's used in various sections of the standards.
        - "Excluded hospitals" is defined and is used in various sections of the standards in conjunction with low occupancy.
        - "Hospital group" is defined and replaces the term "hospital subarea."
        - "Underserved area" is defined and is used in various sections of the standards.
- Section 3: Updated hospital groups methodology which is the former hospital subarea methodology.
- Section 4: Updated the bed need methodology.

- Section 5: Updated consistent with other standards and current practice.
- Section 6: A hospital in a rural or micropolitan statistical area county shall result in a hospital of at least 25 beds, not 50 beds.
    - Added low occupancy criteria under subsection (3) for the receiving licensed hospital under Section 8 – relocation.
    - Renewal of lease for angiography x-ray equipment without volume requirements.
- Section 7: A hospital in a rural or micropolitan statistical area county shall result in a hospital of at least 25 beds, not 50 beds.
    - Added replacement language under subsection (2) consistent with other bed standards.
    - Added low occupancy criteria under subsection (4) for replacement.
- Section 8: Identified "source hospital" under subsection (2).
    - Added low occupancy criteria under subsection (3) for relocation.
- Section 9: Divided requirements into distinct groups: quality assurance, access to care, and monitoring and reporting. Annual volume requirements have been moved to the applicable project delivery requirements subsection.
- Section 15: Added low occupancy criteria under subsection (2) for acquisition.
- Section 16: Added language for quality assurance assessment program (QAAP), civil monetary penalties (CMP), and state and federal code deficiencies consistent with other CON review standards.
- Updated/eliminated Appendices as applicable.
- Addendum for Projects for HIV Infected Individuals has been eliminated.
- Other technical changes.

The revisions to the CON Review Standards for MRI Services received final approval by the CON Commission on September 22, 2011 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 21, 2011. The final language changes include the following:

- Section 10: Removed the pilot language under Section 10(9), and made it a permanent part of the standards.
- Other technical changes.

A second set of revisions to the CON Review Standards for MRI Services received final approval by the CON Commission on June 14, 2012 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the additional revisions became effective September 28, 2012. The final language changes include the following:

- Section 2: Under subsection (1)(bb), added new definition for "MRI-Guided Electrophysiology intervention" or "MRI-Guided EPI" means equipment specifically designed for the integrated use of MRI technology for the purposes of electrophysiology interventional procedures within a cardiac catheterization lab.
    - "Medicaid" – has been updated. (This is a proposed technical amendment.)
    - Modified the definition of "MRI unit" to include: Positron Emission Tomography (PET)/MRI Scanner Hybrids if used for MRI only procedures.
- Section 11: Added new language allowing for an MRI-Guided EPI service to be located at a hospital that has an existing fixed MRI service that has been operational for 36 months and is meeting its minimum volume requirements. The proposed site has an existing and operational therapeutic cardiac catheterization service and is meeting its

minimum volume requirements. Its open heart surgery service must be meeting its minimum volume requirements too. Further, the MRI-guided EPI unit will not be subject to MRI volume requirements, and the applicant shall not utilize the procedures performed on the MRI-guided EPI unit to demonstrate need or to satisfy MRI CON review standards requirements.

- Section 12: Added new language allowing for the use of the PET/MRI scanner hybrid to be used for stand-alone MRI procedures. There must be an approved PET CON, and it must be in compliance with applicable project delivery requirements as set forth in the CON review standards for PET. In addition, the FDA-approved PET/MRI scanner hybrid unit will not be subject to MRI volume requirements, and the applicant shall not utilize the procedures performed on the FDA-approved PET/MRI scanner hybrid unit to demonstrate need or to satisfy MRI CON review standards requirements.
- Section 14: Under subsection (1)(d)(iii), added project delivery requirements for data reporting for the MRI-Guided EPI UNIT similar to intra-operative MRI (IMRI). At a minimum, the data reported shall include how often the MRI-guided EPI unit is used and for what type of services, i.e., electrophysiology or diagnostic.
- Other technical changes.

The revisions to the CON Review Standards for MRT Services/Units received final approval by the CON Commission on September 22, 2011 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 21, 2011. The final language changes include the following:

- Section 1: Modified the language consistent with recent changes in other CON review standards.
- Section 2: A definition that is used only in a certain section has been moved to the applicable section to make it easier for the reader to identify the defined terms
- Section 4: Sections 4 and 10 were combined as these sections related to the initiation of an MRT service, as well as requirements to initiate an HMRT unit.
- Section 5: The replacement section covers both the replacement of the unit as well as replacing the existing service to a new geographical site. Replacement of a unit(s) no longer requires the applicant to meet a set volume requirement. Upgrades to existing MRT units do not require CON review/approval.
- Section 7: Modified the language consistent with recent changes in other CON review standards.
- Section 8: The number of dedicated research MRT units at any one site is limited to two, and the site must already offer MRT services. Added language allowing for dedicated research MRT units to be used primarily for research purposes with the intent being that at least 70% will be dedicated research and no more than 30% clinical visits.
- Section 11: IMRT weight reduced to 2.0 from 2.5.
- Section 12: Modified the language for clarity.
- Section 14: Divided requirements into distinct groups: quality assurance, access to care, monitoring and reporting, and specialized services.
- Appendices updated.
- Other technical changes.

The recommended deregulation for Pancreas Transplantation Services received final approval by the CON Commission on June 14, 2012 and was forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45

days; therefore, the deregulation of Pancreas Transplantation Services became effective September 28, 2012.

The revisions to the CON Review Standards for PET Scanner Services received final approval by the CON Commission on September 22, 2011 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 21, 2011. The final language changes include the following:

- Section 1: Modified the language consistent with recent changes in other CON review standards.
- Section 2: Definitions related to equivalency methodology removed based on a proposed simpler methodology for replacement and expansion.
    - A definition that is used only in a certain section has been moved to the applicable section to make it easier for the reader to identify the defined terms.
- Section 3: Sections 3 and 4 were combined as these sections related to the initiation of a PET service, as well as requirements for mobile services and host site conversions.
    - Added language in Section 3(2) to allow applicants to not only contract for special services from hospitals within the same planning area but also from hospitals that may be near the proposed site but not within the planning area (25-mile radius of the proposed site).
    - Modified the conversion methodology for host sites to convert to a fixed PET scanner service.
    - Simplified Section 3(6) to make it easier to read.
    - Section 3(7)(c) applies both to new fixed PET scanner services as well to host sites that have converted from mobile to fixed services.
    - Section 3(8)(c) continues to allow existing host sites to change from one existing mobile provider to another provider; however, a minimum volume requirement was added at 50 PET equivalents at the applicant host site.
- Section 4: The replacement section covers both the replacement of the scanner as well as replacing the existing service to a new geographical site.
    - Replacement of a scanner(s) no longer requires the applicant to meet a set volume requirement. Upgrades to existing PET scanners, without the replacement of the scanner(s), do not require CON review/approval.
- Section 5: Modified expansion methodology and updated PET equivalents.
    - Section 5(3) added to allow a fixed PET scanner service that has re-initiated a host site at the fixed site to expand to another fixed PET scanner if both the fixed scanner(s) and host site average enough volume to justify expansion (similar volumes as fixed site expansion).
- Section 6: Added language to allow for the first acquisition of a PET scanner service without meeting the maintenance volume requirement. This provision is similar to other standards.
    - Section 6(2) adds a volume requirement threshold for acquisition of a fixed or mobile PET scanner service.
    - Section 6(3) adds a volume requirement threshold to acquire an existing host site.
    - Section 6(4) adds language for renewal of lease.
- Section 7: The number of dedicated research PET scanners is limited to three at any one site, and the site must already offer PET services.

    - Language added allowing for dedicated research PET scanners to be used primarily for research purposes with the intent being that at least 70% will be dedicated research with no more than 30% being clinical scans.
- Section 8: The number of dedicated pediatric research PET scanners is limited to two at any one site.
    - Language added allowing for dedicated pediatric research PET scanners to be used primarily for research purposes with the intent being that at least 70% will be dedicated research with no more than 30% being clinical scans.
- Section 9: New section for positron emission mammography (PEM).
    - Section 9(1) identifies requirements for adding a fixed PEM scanner to an existing fixed PET scanner site.
    - Section 9(2) identifies requirements for adding a mobile PEM scanner to an existing mobile PET scanner service.
    - Section 9(3) identifies requirements for initiating mobile PEM scanner services as a host site.
    - Section 9(4) identifies requirements for adding an existing PEM scanner host site to an existing mobile PEM scanner service.
- Section 11: Divided requirements into distinct groups: quality assurance, access to care, monitoring and reporting, and specialized services for consistency with other CON review standards.
    - Added language under subsection (2)(d) to assure all services set forth in Section 3, subsections (1) through (4), are maintained for the life of the PET scanner service.
    - Added a minimum maintenance volume requirement (500 equivalents), except when an applicant is proposing to replace a PET scanner.
    - Added requirements for PEM scanners.
- Section 17: The methodology has been simplified and the table has been updated.
- Other technical changes.

A second set of revisions to the CON Review Standards for PET Scanner Services received final approval by the CON Commission on June 14, 2012 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the additional revisions became effective September 28, 2012. The final language changes include the following:

- Section 2(1)(q): Added to the existing definition of "PET scanner" to include: FDA-Approved PET/Magnetic Resonance Imaging (MRI) scanner hybrids. If the FDA-Approved PET/MRI scanner hybrid will be used for MRI scans only in conjunction with the PET scan, then no separate CON is required for that MRI use.
- Section 3(4)(d): Added language to exempt a host site that is initiating FDA-approved PET/MRI scanner hybrid service(s) from having to cease operation as a host site so that it can continue to conduct PET only scans.
- Other technical changes.

The revisions to the CON Review Standards for Surgical Services received final approval by the CON Commission on December 15, 2011 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 February 27, 2012. The final language changes include the following:

- Section 1: Modified for consistency with other CON review standards. Moved subsection 3 to Section 2 within definition (m), “Freestanding surgical outpatient facility.”
- Section 2: Definitions used only in certain section(s) have been moved to the applicable section to make it easier for the reader to identify the defined terms.
- Section 3: Modified to reflect either 1.0 exemption for a room used exclusively for trauma care or a 0.5 exemption for a room that is not used exclusively for trauma care.
- Section 5: The replacement section will cover both the replacement of the OR as well as replacing the existing OR to a new geographical site.
- Section 8: Added language to define and outline requirements for a hybrid operating room/cardiac catheterization laboratory (OR/CCL).
- Section 9: Modified language consistent with other CON review standards on Medicaid participation requirement.
- Section 10: Divided requirements into distinct groups: quality assurance, access to care, and monitoring and reporting for consistency with other CON review standards.
- 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 (Eff. 3/29/12)
Gail A. Clarkson
Bradley N. Cory (Appointment expired 4/9/12 and replaced by Gail A. Clarkson)
Kathleen Cowling, DO
Charles M. Gayney
Edward B. Goldman, JD
Robert L. Hughes
Brian A. Klott
Gay L. Landstrom
Suresh Mukherji, MD
Michael A. Sandler, MD (Appointment expired 4/9/12 and replaced by Luis A. Tomatis, 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**.