MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED PROGRAM

ANNUAL ACTIVITY REPORT

October 2008 through September 2009
(FY2009)

Michigan Department of
Community Health

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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 21st report to the Commission and covers the period beginning October 1, 2008 through September 30, 2009 ("FY2009"). Data contained in this report may differ from prior reports due to updates subsequent to each report's publishing date.

Historical Overview

In 1974, Congress passed the National Health Planning and Resources Development Act (PL 93-641) that encouraged states to establish a CON program as a vehicle for health services planning. The law was repealed in 1986. Michigan's law was not repealed and, during the 1980s, it became evident that the expectations and decisions of Michigan's CON program were unclear and unpredictable to many applicants. As a result, the CON Reform Act of 1988 was passed that created a standards development process and reduced the number of services requiring a CON. Since these reforms, the number of CON denials and appeals has declined.

Administration

The MDCH through its Health Policy 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 standard advisory committees 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 private consultants or request the Department to contract with any private organization for professional and technical assistance and advice or other services to assist the Commission in carrying out its duties and functions.

The MDCH through its 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.

During FY 2009, 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-Serv). The first module was released in 2006. Today, the vast majority of Letters of Intent, CON applications, and amendments are filed online. In addition, the Section released new features in during the fiscal year including an online application fee payment system, additional search features, and enhanced reports and forms.

In August 2009, the Michigan CON e-Serv was recognized by The National Association of State Chief Information Officers (NASCIO) as one of 30 outstanding state information technology initiatives. Michigan CON e-Serv was nominated for best application in the field of Digital Government along with the State of Nebraska and its Court Document E-filing and the State of Utah with On the Spot Renewal System and Highway Patrol Safety Inspections.

The Evaluation Section also released in April a 2008 Michigan Atlas of Licensed Health Facilities collaborating with the Michigan State University Department of Geography. In

addition, the Section released an online annual survey system allowing approved CON holders to report annual utilization data as required by Code and Standards.

These three initiative have greatly increased the availability of CON related data and information 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 Bureau,
  - Appeal if applicant disagrees with the Proposed Decision issued,
- Issuance of the Final Decision by the MDCH Director.

Types of Reviews

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.

In FY2009, there were 115 applications for nonsubstantive review, 78 for substantive individual review and 26 for comparative review, for a total of 219 applications received. Nineteen (19) applications were withdrawn prior to a proposed decision being issued. These applications are usually withdrawn because the applicant cannot demonstrate the need requirements set forth in the applicable standards.

Final Decisions

In FY2009, 271 applications for CON review were approved, including one (1) emergency CON approvals. Twenty-seven (27) final decisions included conditions, while three (3) were disapproved.

Report

The following report presents information about the nature of these CON applications and decisions. Note that the data presented represents some applications that were carried over from last fiscal year and others that have been carried over into next fiscal year.

HISTORICAL OVERVIEW OF MICHIGAN'S CERTIFICATE OF NEED PROGRAM

In 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.

Michigan has had a state CON program since the early 1970s. Over the years, the law has been amended several times. 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 CON 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, making decisions on CON applications consistent with the review standards.

In 1993, additional amendments to the Act required ad hoc committees to be appointed by the Commission to provide expert assistance in the formation of the review standards. And again in 2002, amendments expanded the CON Commission to 11 members, eliminated ad hoc committees, and established the use of standard advisory committees or other private consultants/organizations for professional and technical assistance.

The CON program is now more predictable so that applicants reasonably can 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

CON Responsibilities

Certificate of Need Commission Responsibilities: 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 FY2009.

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 Responsibilities: The Policy Section within the Department 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.

The Evaluation Section has operational responsibility for the program, including providing assistance to applicants prior to and throughout the CON process. The section is also responsible for reviewing all letters of intent ("LOI") and applications as prescribed by the Administrative Rules. Based on the LOI, staff determines if a proposed project requires a CON. If a CON is required, staff identifies the appropriate application forms to the applicant for completion 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.

In addition to the application reviews, the Evaluation Section also 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 Rules allow actual project costs to exceed approved costs by a specified amount due to the difficulty in estimating construction and other capital costs at the time an application is filed. Currently, no fee is charged for processing amendments.

The Evaluation Section also provides the Michigan State Hospital Finance Authority ("MSHFA") with information when hospitals request financing through MSHFA bond issues and Hospital Equipment Loan Program ("HELP") loans. This involves advising MSHFA on whether a CON is required for the items that will be bond financed and if a required CON has been obtained. During FY2009, the Section's financial analyst reviewed 4 bond and HELP loan requests.

CERTIFICATE OF NEED APPLICATION 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 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 a completed application with the Department and, if applicable, the regional CON 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 that involve projects such as certain equipment replacements and changes in ownership 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 CON law and the applicable CON Review Standards.

Proposed Decision. The Bureau of Health Systems 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.

Acceptance and Appeal of Decision. If the proposed decision is not appealed, a final decision will be signed by the Director in accordance with MCL 333.22231. If a hearing is requested, the final decision is not issued by the Director until completion of the hearing.

LETTERS OF INTENT

The CON Administrative Rules, specifically Rule 9201, provides that LOIs must be processed within 15 days of receipt. Processing an LOI includes entering data in the program's management information system, verifying proof of documentation to do business in Michigan and ownership, determining the type of review for the proposed project, and notifying 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
FY2005 - FY2009

	FY2005	FY2006	FY2007	FY2008	FY2009
LOIs Received	536	562	582	521	335
Processed within 15 Days	532	548	579	517	333
Percent Processed within 15 Days	99%	98%	99%	99%	99%

In FY2009, almost 100% of Letters of Intent received by the Department were filed by the applicants using the new online Web-based system. Further, all Letters of Intent were processed and are available for viewing on the online system. The system allows for quicker receipt and processing of Letters of Intent by the Evaluation Section, as well as modifying these letters by applicants when needed.

TYPES OF CERTIFICATE OF NEED APPLICATION REVIEWS

The Administrative Rules also establish three types of project reviews: nonsubstantive, substantive, and comparative. As discussed in the previous section, 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 some of the types of projects that potentially would be eligible for review on a nonsubstantive basis:

- Acquire an existing health facility;
- Replace and relocate existing 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 and 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 review cycle begins when the determination is made that the project requires a 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 comparative window date exceed the current need. A comparative window date is one of the three dates during the year on which projects potentially subject to comparative review must be filed. Those dates are February 1, June 1, and October 1 (or the first working day following any of those dates).

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

Figure 1 delineates services/beds subject to comparative review.

FIGURE 1: Services/Beds Subject to Comparative Review in FY2009*	
Neonatal Intensive Care	Nursing Home Beds for Special Population Groups
Hospital Beds	Psychiatric Beds
Hospital Beds (HIV)	Transplantations (excluding Pancreas)
Nursing Home Beds	

*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
FY2005 - FY2009

	FY2005	FY2006	FY2007	FY2008	FY2009
Nonsubstantive	127	162	170	183	115
Substantive Individual	162	212	135	165	78
Comparative	13	9	15	37	26
TOTALS	302	383	320	385	219

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
FY2005 - FY2009

	FY2005	FY2006	FY2007	FY2008	FY2009
Applications Received*	302	383	320	388	220
Processed within 15 Days	302	383	320	387	219
Percent Processed within 15 Days	100%	100%	100%	100%	100%

*Includes Emergency CON applications

Table 4 provides the number and percent of applications incomplete when submitted to the Department. Prior to reviewing an application, the Evaluation Section examines each application to determine if all of the necessary information requested in the Letter of Intent has been received, as well as other information needed to comply with applicable statutory requirements and CON Review Standards. This phase of the review process involves 30 days: 15 days for the Section to request additional information and 15 days for the applicant to respond to the request.

TABLE 4
INCOMPLETE APPLICATIONS
FY2005 - FY2009

ALL APPLICATIONS	FY2005	FY2006	FY2007	FY2008	FY2009
Complete	38	18	72	111	77
Incomplete	264	365	248	277	143
Percent Incomplete	87%	95%	78%	71%	65%

Table 5 provides an overview of the average number of days taken by the Evaluation Section to complete reviews by type.

TABLE 5
AVERAGE NUMBER OF DAYS IN REVIEW CYCLE BY REVIEW TYPE
FY2005 - FY2009

	FY2005	FY2006	FY2007	FY2008	FY2009
Nonsubstantive	35	35	37	40	38
Substantive Individual	112	109	126	116	113
Comparative	146	108	132	151	260*

Note: Average review cycle accounts for extensions including review of new standards and requests by applicants.
* In FY2009 average days for comparative review applications increased substantially due to multiply revisions to the nursing homes review standards.

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 MDCH 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
FY2005 - FY2009

	Nonsubstantive		Substantive		Comparative	
	Issued	Within 45 days	Issued	Within 120 days	Issued	Within 150 days
FY2005	104	95%	169	99%	10	90%
FY2006	162	100%	175	99%	3	100%
FY2007	152	99%	162	98%	15	100%
FY2008	176	99%	145	99%	6	50%
FY2009	130	100%	114	99%	20	90%

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

TABLE 7
COMPARISON OF PROPOSED DECISIONS BY DECISION TYPE
FY2005 - FY2009

	Approved	Approved w/ Conditions	Disapproved	Percent Disapproved	TOTAL
FY2005	199	88	5	2%	292
FY2006	213	126	4	1%	343
FY2007	263	60	10	3%	333
FY2008	282	50	5	2%	337
FY2009	240	25	19	7%	284

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 compares the number of applications submitted to the Department and the number of final decisions issued.

TABLE 8
APPLICATIONS SUBMITTED FOR REVIEW AND FINAL DECISIONS
FY2005 - FY2009

	FY2005	FY2006	FY2007	FY2008	FY2009
Applications Submitted	302	383	320	388	220
Final Decisions	294	345	319	354	271

Note: Not all applications received in a given year receive a decision in that same year.

Figures 2 illustrate final decisions issued by project review types.

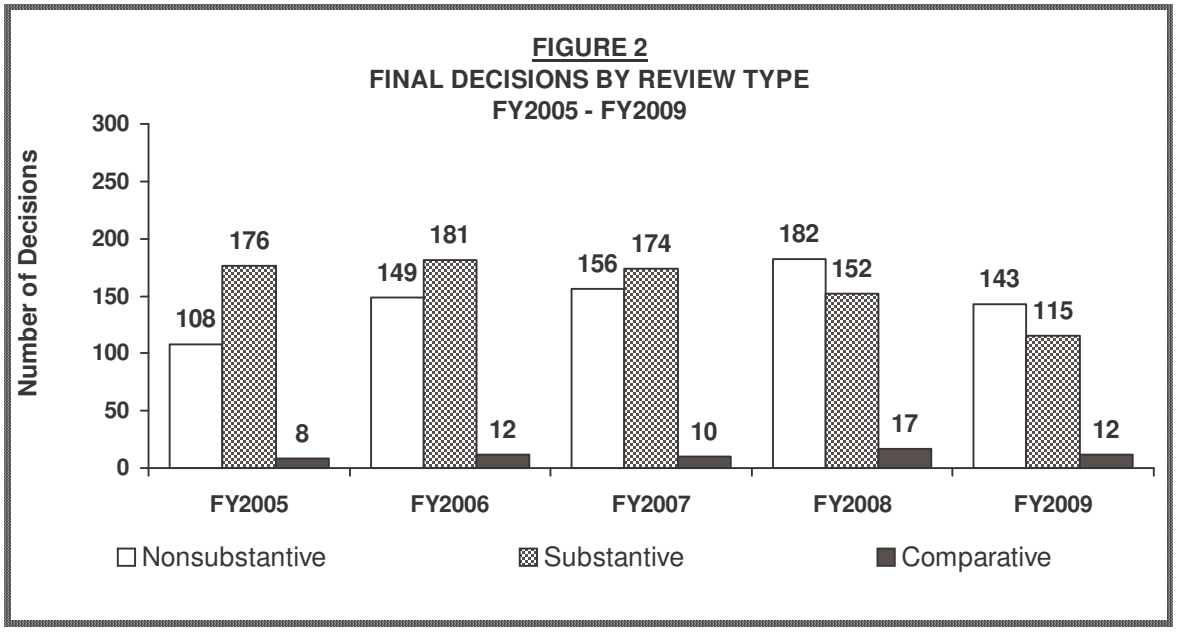

Table 9 summarizes final decisions by review categories defined in MCL 333.22209(1) and as summarized below:

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 imager services, computerized 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 2nd 2009, the covered capital expenditure threshold was $2,932,500. The threshold is updated every January in accordance with Part 222.

TABLE 9
FINAL DECISIONS ACTIVITY CATEGORY
FY2005 - FY2009

Approved	**FY2005**	**FY2006**	**FY2007**	**FY2008**	**FY2009**
Acquire, Begin, or Replace a Health Facility	54	57	51	71	49
Change in Bed Capacity	18	26	29	20	37
Covered Clinical Services	222	255	237	228	190
Covered Capital Expenditures	23	33	30	30	35
Disapproved					
Acquire, Begin, or Replace a Health Facility	1	2	2	2	1
Change in Bed Capacity	2	0	1	1	2
Covered Clinical Services	3	2	1	2	0
Covered Capital Expenditures	1	0	0	1	0

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
FY2005 - FY2009

	Approved	Approved With Conditions	Disapproved	TOTALS
Number of Final Decisions				
FY2005	200	88	6	294
FY2006	234	106	3	345
FY2007	257	58	4	319
FY2008	291	59	4	354
FY2009	240	27	3	271
Total Project Costs				
FY2005	$872,652,430	$312,589,694	$19,442,339	$1,204,684,463
FY2006	$1,559,834,963	$837,565,409	$22,706,628	$2,397,456,372
FY2007	$1,577,574,167	$325,128,269	$1,765,604	$1,904,468,040
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

Note: Final decisions include Emergency CONs.

EMERGENCY CERTIFICATES OF NEED

Table 11 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 11
EMERGENCY CON DECISIONS ISSUED
FY2005 - FY2009

	FY2005	FY2006	FY2007	FY2008	FY2009
Emergency CONs Issued	9	3	5	3	1
Issued within 10 Working Days	9	3	5	2	1

AMENDMENTS

The Rules allow an applicant to request to amend an approved CON for projects that are not 100 percent 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 to approved CONs 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
FY2005 - FY2009

	FY2005	FY2006	FY2007	FY2008	FY2009
Amendments Received	97	77	61	68	90
Amendment Decisions Issued	77	97	61	71	91
Issued within Required Time Frame	54	84	60	51	85
Percent Issued within Required Time Frame	70%	87%	98%	71%	93%

CERTIFICATE OF NEED ACTIVITY SUMMARY COMPARISON

Table 13 provides a comparison for various stages of the CON process.

TABLE 13
CON ACTIVITY COMPARISON
FY2005 - FY2009

	Number of Applications	% Change From Previous Year	Total Project Costs	% Change From Previous 4-Year-Average
Letters of Intent Submitted				
FY2005	536	(12%)	$2,171,399,994	N/A
FY2006	562	5%	$3,156,853,978	N/A
FY2007	582	4%	$3,316,323,030	N/A
FY2008	521	(11%)	$3,032,871,348	N/A
FY2009	335	(55%)	$851,958,151	(243%)
Applications Submitted				
FY2005	302	(13%)	$1,357,978,749	N/A
FY2006	383	27%	$2,696,930,804	N/A
FY2007	320	(16%)	$3,097,185,206	N/A
FY2008	388	21%	$2,577,833,078	N/A
FY2009	219	(77%)	$604,642,399	(302%)
Final Decisions Issued				
FY2005	294	-5%	$1,204,684,463	N/A
FY2006	345	16%	$2,397,456,372	N/A
FY2007	319	(8%)	$1,904,468,040	N/A
FY2008	354	11%	$3,539,943,543	N/A
FY2009	271	(31%)	$1,110,493,175	(104%)

Note: Final Decisions Issued include Emergency CONs.

COMPLIANCE ACTIONS

There were 379 projects requiring follow-up for FY2009 based on the Department's Monthly Follow-up/Monitoring Report as shown in **Table 14**.

TABLE 14
FOLLOW UP AND COMPLIANCE ACTIONS
FY2005 - FY2009

	FY2005	FY2006	FY2007	FY2008	FY2009
Projects Requiring Follow-up	298	310	413	417	379
Compliance Orders Issued	2	0	2	1	4

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** below.

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
FY2005 - FY2009

CON Fee	FY2005	FY2006	FY2007	FY2008	FY2009
$ 0*	10	4	6	4	1
$1,500	54	84	75	128	103
$5,500	119	191	141	151	76
$8,500	48	104	98	109	39
TOTALS	302	383	320	392	219

* No fees are required for Emergency CON and swing beds applications.
Note: Table 15 may not match application fee totals in Table 16 because Table 16 accounts for refunds, overpayments, MSHFA funding, etc.

Table 16 provides information on CON costs and source of funds.

TABLE 16
CON PROGRAM
COST AND REVENUE SOURCES FOR FY2005 – FY2009

	FY2005	FY2006	FY2007	FY2008	FY2009
Program Cost	$1,287,315	$1,877,100	$1,741,300	$1,960,655	$1,871,395
Application Fees	$1,396,223	$1,884,849	$1,688,000	$1,743,926	$1,095,048
Fees % of Costs	100%+	100%	97%	89%	59%

Note: FY 2005-2008 figures are revised.
Source: MDCH Budget and Finance Administration.

Section 22215(6) states "If the reports received under section 22221(f) indicate that the certificate of need application fees collected under section 20161(2) have not been within 10% of 3/4 the cost to the department of implementing this part, the commission shall make recommendations regarding the revision of those fees so that the certificate of need application fees collected equal approximately 3/4 of the cost to the department of implementing this part." The fee information for FY2009 indicates the CON program is not in compliance with Section 22215(6).

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY2009, the CON Commission revised the review standards for Bone Marrow Transplantation (BMT) Services, Hospital Beds, Magnetic Resonance Imaging (MRI) Services, and Megavoltage Radiation Therapy (MRT) Services/Units.

The revisions to the CON Review Standards for BMT Services received final approval by the CON Commission on September 16, 2008 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 13, 2008.

The final language change includes a modification under Section 8(1)(g) to change the period of the extension for the prospective payment system (PPS) exemption.

The revisions to the CON Review Standards for Hospital Beds received final approval by the CON Commission on December 9, 2008 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 2, 2009. The final language changes include the following:

- Definitions for "acquiring a hospital," "host hospital," and "licensed site" clarified based on current Department practice.
- Clarified language under Section 6(2)(b) & (b)(i), renewal of lease for long-term (acute) care hospitals (LTACH) and subsequent addition of beds for LTACHs and the host hospital respectively, based on current Department practice.
- Updated Appendix A.
- Re-calculated the bed need with the base year of 2006 and the planning year of 2011. Updated Appendix C.
- Other technical changes.

The revisions to the CON Review Standards for MRI Services received final approval by the CON Commission on September 16, 2008 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 13, 2008. The final language changes include the following:

- Definition for intra-operative magnetic resonance imaging (IMRI).
- Added a new Section 11, “Requirements for approval – applicants proposing to initiate, replace, or acquire a hospital based IMRI.” This new section includes the following provisions:
  - The proposed site is a licensed hospital under part 215 of the Code.
  - The proposed site has an existing fixed MRI service that has been operational for the previous 36 consecutive months and is meeting its minimum volume requirements.
  - The proposed site has an existing and operational surgical service and is meeting its minimum volume requirements pursuant to the CON Review Standards for Surgical Services.
  - The applicant shall have experienced one of the following: 1) at least 1,500 oncology discharges in the most recent year of operation; 2) at least 1,000 neurological surgeries in the most recent year of operation; or 3) at least 7,000

pediatric (<18 years old) discharges (excluding normal newborns) and at least 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.
    - The proposed IMRI unit must be located in an operating room or a room adjoining an operating room allowing for transfer of the patient between the operating room and this adjoining room.
    - Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under the section unless the patient meets one of the following criteria: 1) the patient has been admitted to an inpatient unit; or 2) the patient is having the study performed on an outpatient basis, but is in need of general anesthesia or deep sedation as defined by the American Society of Anesthesiologists.
    - The approved IMRI unit will not be subject to MRI volume requirements.
    - The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need or to satisfy MRI CON Review Standards requirements.
    - The applicant agrees to operate the IMRI unit in accordance with all applicable project delivery requirements set forth in the standards.
    - The provisions are part of a pilot program approved by the CON Commission and shall expire and be of no further force and effect, and shall not be applicable to any application which has not been submitted by December 31, 2010.
- Data to be reported shall include, at a minimum, how often the IMRI unit is used and for what type of services, i.e., intra-operative 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 16, 2008 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 13, 2008. The final language changes include the following:

- Modified the definition of “heavy particle accelerator” to specifically include carbon ions.
- Added definitions for “high MRT (HMRT) unit” and “hospital MRT service” for purposes of Section 10.
- Modified the definitions for “non-special MRT unit” and “special purpose MRT unit.”
- Removed references to heavy particle accelerator under sections 5 and 6 since they would no longer be considered special purpose MRT units.
- Added a new Section 10, “Requirements for approval – applicants proposing to initiate an MRT service utilizing an HMRT unit.” This new section includes the following provisions:
    - The applicant shall be a single legal entity authorized to do business in Michigan.
    - The applicant shall be a collaborative consisting of, at a minimum, at least 40% of all Michigan hospital MRT services with more than 30,000 equivalent treatment visits (ETVs). Utilizing the April 30, 2008 revised list published by the Department, there are nine services with more than 30,000 ETVs, meaning that four would have to participate in the collaborative.
    - The collaborative shall include hospital MRT services from more than one planning area from either or both of the following: i) the participating services under subsection (b) (those above 30,000 ETVs); ii) hospital MRT services with the highest number ETVs in a planning area.
    - For purposes of Section 10, the ETVs shall be those from the April 30, 2008 list (revised) published by the Department. The list will be updated every three years.

- Language under Section 10(1)(e) describes participation in only **one** collaborative and includes MRT services that are owned by, under common control of, or has a common parent.
- Language under Section 10(1)(f) requires those MRT services that have been approved but not operational, or have a pending application, for a heavy particle accelerator to surrender the CON or application in order to participate in the proposed collaborative for an MRT service utilizing an HMRT unit. The CON or application, as applicable, must be surrendered when the application is approved.
- Language under Section 10(1)(g) requires those MRT services that have been approved and are operational for a heavy particle accelerator to surrender the CON in order to participate in the proposed collaborative for an MRT service utilizing an HMRT unit. The CON must be surrendered when the HMRT unit becomes operational.
- The applicant shall provide documentation of its process, policies, and procedures, acceptable to the Department, that allows any other interested entities to participate in the collaborative utilizing an HMRT unit.
- The applicant shall provide an implementation plan, acceptable to the Department, for financing and operating the proposed MRT service utilizing an HMRT unit which includes how physician staff privileges, patient review, patient selection, and patient care management shall be determined.
- MRT services utilizing an HMRT unit shall be provided to adult and pediatric patients.
- The MRT service utilizing an HMRT shall have simulation capabilities available for use in treatment planning.
- MRT services utilizing an HMRT unit demonstrate compliance with the staffing requirements of Section 4(3).
- Additional project delivery requirements for MRT services utilizing an HMRT unit have been included:
    - ✓ All patients treated shall be evaluated for potential enrollment in research studies focusing on the applicability and efficacy of utilizing an HMRT unit for treatment of specific cancer conditions. The number of patients treated, number enrolled in research studies, and the types of cancer conditions involved, shall be provided to the Department as part of the con Annual Survey.
    - ✓ Upon completion of any study, and authorization by study sponsor, the findings and summary of any research studies, consistent with patient confidentiality, shall be provided to the Department by the applicant.
    - ✓ The MRT service utilizing an HMRT unit shall provide the Department, on an annual basis, following the initiation of the service, with updates to the information provided and approved by the Department pursuant to subsections 10(1)(h), (i), (j), (k), and 10(2).
    - ✓ On an annual basis, following the initiation of the service, the Department will assess the affordability of the project by evaluating the “Hospital Cost Report” and any other applicable information supplied to the Centers of Medicare and Medicaid Services (CMS) and the Michigan Medical Services Administration (MSA). This allows for MDCH oversight of affordability.
    - ✓ Upon review, by the Department, of the information submitted under c) and d) above, and the Department’s finding that the service has not fulfilled project delivery requirements, the Department may order changes

with regard to the provision of the HMRT service to assure fulfillment of project delivery requirements. The Department may elect to verify the information and data through on-site review of appropriate records.

- Replaced reference to heavy particle accelerator with HMRT units where applicable in the project delivery requirements and Table 1 in Section 13.
- Updated the following project delivery requirement [Section 16(1)(c)(iv)] as shown: " All MRT treatments shall be performed pursuant to a radiation oncologist and at least one radiation oncologist will be immediately available during the operation of the unit(s)." Immediately available is already defined in the standards as "continuous availability of direct communication with the MRT unit in person or by radio, telephone, or telecommunication."
- Other technical changes.

CERTIFICATE OF NEED COMMISSIONERS

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