MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED PROGRAM

ANNUAL ACTIVITY REPORT

October 2007 through September 2008
(FY2008)

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 20th report to the Commission and covers the period beginning October 1, 2007 through September 30, 2008 ("FY2008"). 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 The law was repealed in 1986. Michigan's law was not repealed and, during the 1980s, it became evident that the expectations and decisions of Michigan's CON program were unclear and unpredictable to many applicants.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 Program Review 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 FY2008, the Program Review Section continued its work to improve the online application and management information system. The first phase of the system was released in January 2006 that included an online letter of intent and management information system. In addition, a guest feature was released in June 2006 allowing applicants and non-applicants the ability to monitor pending and approved CONs statewide. The online application module for nonsubstantive and emergency applications as well as amendments was released in March 2007. The final modules for substantive applications and online payments of application fees were released in April and November fo 2008, respectively. Potential comparative applications will not be part of the online system until further refinements are made.

The Program Review Section also is working to develop an online survey system to be released in 2009 to allow approved entities to report annual utilization data as required by Code and Standards. In addition, the Section is working with the Department of Geography at Michigan State University to develop interactive maps identifying all licensed health facilities and other medical facilities with covered clinical services operating in the State.

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 at a site that is not currently licensed for that type of 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 Program Review Section,
- Issuance of Proposed Decision by the Bureau of Health Systems ("BHS") in which the Program Review Section resides,
    - 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 (involving competitive applications for limited resources by two or more applicants). 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 FY2008, there were 183 applications for nonsubstantive review, 165 for substantive individual review and 37 for comparative review, for a total of 385 applications received. Seventeen (17) 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 FY2008, 354 applications for CON review were approved, including three (3) emergency CON approvals. Forty-nine (49) final decisions included conditions, while four (4) 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 Section inside the Department is responsible for day-to-day operations of the program, including 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 FY2008.

Pursuant to PA 619 of 2002, effective March 31, 2003, 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 Program Review 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 Program Review 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 Program Review 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 FY2008, the Section's financial analyst reviewed 17 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 Program Review 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 Program Review 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 Program Review 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
FY2004 - FY2008

	FY2004	FY2005	FY2006	FY2007	FY2008
LOIs Received	608	536	562	582	521
Processed within 15 Days	N/A	532	548	579	517

Note: FY2004 not available. Tracking system to measure compliance for this Rule developed in 2005.

In FY2008, 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 Program Review 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 FY2008*	
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
FY2004 - FY2008

	FY2004	FY2005	FY2006	FY2007	FY2008
Nonsubstantive	101	127	162	170	183
Substantive Individual	237	162	212	135	165
Comparative	10	13	9	15	37
TOTALS	348	302	383	320	385

Table 3 provides a summary of applications received and processed in accordance with Rule 9201. The Rule requires the Program Review 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 - FY2008

	FY2005	FY2006	FY2007	FY2008
Applications Received	302	383	320	388
Processed within 15 Days	302	383	320	387

Note: Tracking system to measure compliance for this Rule developed in 2005.

Table 4 provides the number and percent of applications incomplete when submitted to the Department. Prior to reviewing an application, the Program Review 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
FY2004 - FY2008

ALL APPLICATIONS	FY2004	FY2005	FY2006	FY2007	FY2008
Complete	110	38	18	72	111
Incomplete	238	264	365	248	277
Percent Incomplete	68%	87%	95%	78%	71%

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

TABLE 5
AVERAGE NUMBER OF DAYS IN REVIEW CYCLE BY REVIEW TYPE
FY2004 - FY2008

	FY2004	FY2005	FY2006	FY2007	FY2008
Nonsubstantive	40	35	35	37	40
Substantive Individual	117	112	109	126	116
Comparative	169	146	108	132	151

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 Program Review 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 - FY2008

	Nonsubstantive		Substantive		Comparative	
	Issued	Within 45 days	Issued	Within 120 days	Issued	Within 150 days
FY2005	104	99	169	167	10	9
FY2006	162	162	175	173	3	3
FY2007	152	150	162	158	15	15
FY2008	176	174	145	143	6	3

Note: Tracking system to measure compliance for this Rule developed in 2005.

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

TABLE 7
COMPARISON OF PROPOSED DECISIONS BY DECISION TYPE
FY2004 - FY2008

	Approved	Approved w/ Conditions	Disapproved	Percent Disapproved	TOTAL
FY2004	211	82	17	5%	310
FY2005	199	88	5	2%	292
FY2006	213	126	4	1%	343
FY2007	263	60	10	3%	333
FY2008	282	50	5	2%	337

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
FY2004 - FY2008

	FY2004	FY2005	FY2006	FY2007	FY2008
Applications Submitted	348	302	383	320	388
Final Decisions	308	294	345	319	354

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.

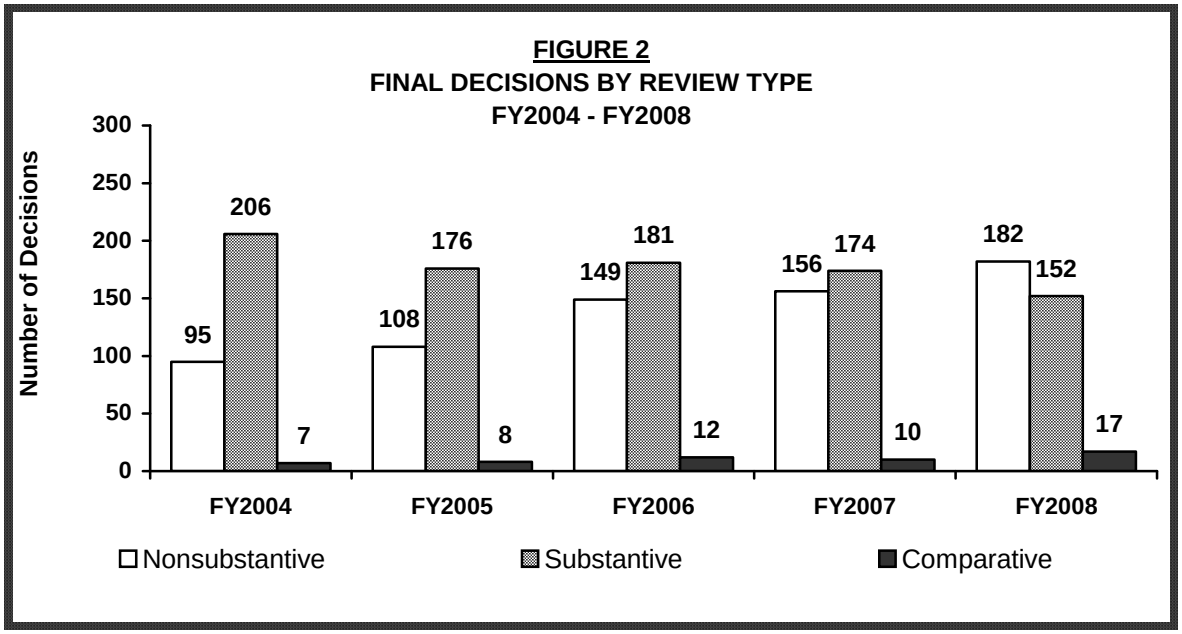

Table 9 summarizes final decisions by review categories defined in MCL 333.22209(1) and as summarized below:

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 2008, the covered capital expenditure threshold was $2,872,500. The threshold is updated every January in accordance with Part 222.

TABLE 9
FINAL DECISIONS ACTIVITY CATEGORY
FY2004 - FY2008

Approved	**FY2004**	**FY2005**	**FY2006**	**FY2007**	**FY2008**
Acquire, Begin, or Replace a Health Facility	75	54	57	51	71
Change in Bed Capacity	29	18	26	29	20
Covered Clinical Services	211	222	255	237	228
Covered Capital Expenditures	30	23	33	30	30
Disapproved					
Acquire, Begin, or Replace a Health Facility	2	1	2	2	2
Change in Bed Capacity	2	2	0	1	1
Covered Clinical Services	3	3	2	1	2
Covered Capital Expenditures	1	1	0	0	1

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
FY2004 - FY2008

	Approved	Approved With Conditions	Disapproved	TOTALS
Number of Final Decisions				
FY2004	221	81	6	308
FY2005	200	88	6	294
FY2006	234	106	3	345
FY2007	257	58	4	319
FY2008	291	59	4	354
Total Project Costs				
FY2004	$933,587,233	$715,077,786	$28,681,746	$1,677,346,765
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

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
FY2004 - FY2008

	FY2004	FY2005	FY2006	FY2007	FY2008
Emergency CONs Issued	1	9	3	5	3
Issued within 10 working days	N/A	9	3	5	2

Note: FY2004 not available. Tracking system to measure compliance for this Rule developed in 2005.

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
FY2004 - FY2008

	FY2004	FY2005	FY2006	FY2007	FY2008
Amendments Received	70	97	77	61	68
Amendment Decisions Issued	N/A	77	97	61	71
Issued within required time frame	N/A	54	84	60	51

Note: FY2004 not available. Tracking system to measure compliance for this Rule developed in 2005.

CERTIFICATE OF NEED ACTIVITY SUMMARY COMPARISON

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

TABLE 13
CON ACTIVITY COMPARISON
FY2004 - FY2008

	Number of Applications	% Change From Previous Year	Total Project Costs	% Change From Previous Year
Letters of Intent Submitted				
FY2004	608	31%	$1,809,242,755	(12%)
FY2005	536	(12%)	$2,171,399,994	20%
FY2006	562	5%	$3,156,853,978	45%
FY2007	582	4%	$3,316,323,030	5%
FY2008	521	(11%)	$3,032,871,348	(9%)
Applications Submitted				
FY2004	348	24%	$1,697,271,072	39%
FY2005	302	(13%)	$1,357,978,749	(20%)
FY2006	383	27%	$2,696,930,804	98%
FY2007	320	(16%)	$3,097,185,206	15%
FY2008	388	21%	$2,577,833,078	(17%)
Final Decisions Issued				
FY2004	308	14%	$1,677,346,765	57%
FY2005	294	-5%	$1,204,684,463	(28%)
FY2006	345	16%	$2,397,456,372	99%
FY2007	319	(8%)	$1,904,468,040	(21%)
FY2008	354	11%	$3,539,943,543	86%

COMPLIANCE ACTIONS

There were 310 projects requiring follow-up for FY2008 based on the Department's Monthly Follow-up/Monitoring Report as shown in **Table 14**.

TABLE 14
FOLLOW UP AND COMPLIANCE ACTIONS
FY2004 - FY2008

	FY2004	FY2005	FY2006	FY2007	FY2008
Projects Requiring Follow-up	301	298	310	413	111
Compliance Orders Issued	1	2	0	2	1

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
FY2004 - FY2008

CON Fee	FY2004	FY2005	FY2006	FY2007	FY2008
$ 0*	5	10	4	6	4
$1,500	N/A	54	84	75	128
$5,500	N/A	119	191	141	151
$8,500	N/A	48	104	98	109
TOTALS	348	302	383	320	392

* 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 FY2004 – FY2008

	FY2004	FY2005	FY2006	FY2007	FY2008
Program Cost	$1,274,306	$1,287,315	$1,877,110	$1,665,800	$1,760,300
Application Fees	$951,146	$1,331,409	$1,884,894	$1,666,500	$1,752,000
Fees % of Costs	75%	100%+	100%+	100%+	99%

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 FY2008 indicates the CON program is in compliance with Section 22215(6).

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY2008, the Certificate of Need Commission revised the review standards for Cardiac Catheterization (CC) Services, Computed Tomography (CT) Scanner Services, Magnetic Resonance Imaging (MRI) Services, Megavoltage Radiation Therapy (MRT) Services/Units, Neonatal Intensive Care (NICU) Services/Beds, Nursing Home and Hospital long-term Care Unit (NH-HLTCU) Beds, Open Heart Surgery (OHS) Services, Psychiatric Beds and Services, Surgical Services, and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units.

The revisions to the CON Review Standards for CC Services received final approval by the CON Commission on December 11, 2007 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 25, 2008. The final language changes include, but are not limited to, the following:

- Facilities providing cardiac catheterization services in Michigan are required to participate in the American College of Cardiology National Cardiovascular Data Registry's Cath/PCI Registry (ACC-NDCR).
- Eliminated physician volume requirements for adult diagnostic cardiac catheterization services.
- Institutional volume shall be a minimum of 600 procedure equivalents in the category of pediatric cardiac catheterizations to be performed annually.
- Modified computations for cardiac catheterization equivalents, procedures, and weights.
- Added language to allow for cardiac permanent pacemaker/ICD device implantations to be performed in diagnostic cardiac catheterization laboratories in hospitals that do not provide therapeutic cardiac catheterization services.
- Revised definition of Replace/Upgrade to state "that involves a capital expenditure of $500,000 or more in any consecutive 24-month period which results in the applicant operating the same number of cardiac catheterization laboratories."
- Require facilities proposing to initiate a pediatric cardiac catheterization service to initiate the following guidelines extracted from The American Academy of Pediatrics (AAP) for Pediatric Cardiovascular Centers (March 2002):
    - A board certified cardiologist with training in pediatric catheterization procedures to direct the pediatric catheterization laboratory
    - Standardized equipment as outlined in AAP Guidelines Publication
    - On-Site ICU as outlined in AAP Guidelines Publication
    - On-Site Pediatric Open Heart Surgery
- Defined Intra-Vascular Catheterization within Section 11, Methodology for Computing Cardiac Catheterization Equivalents – Procedures And Weights
- Other technical changes.

The revisions to the CON Review Standards for CT Scanner Services received final approval by the CON Commission on March 11, 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 May 5, 2008. The final language changes include, but are not limited to, the following:

- Added language that would allow for the relocation of a unit(s) or a "service."
- Modified replace/upgrade definition. Upgrade has been removed, and replace has been defined as an equipment change in the existing scanner which requires a change in the

Radiation Safety Certificate.

- Added language that would allow for replacement of a scanner currently operating below minimum volume requirements (7500 CT equivalents) to receive a one time exemption if the following conditions are satisfied:
  - The existing scanner is performing at least 5000 CT equivalents in the preceding 12-month period.
  - The existing scanner at one point met the minimum volume requirements.
  - The existing scanner is fully depreciated.
- Added language that would allow for replacement of a scanner currently operating below minimum volume requirements (7500 CT equivalents) on an academic medical center campus to receive a one time exemption if the existing scanner is fully depreciated.
- Modified language that would require projection of physician referral commitments for initiation of a service to be based on actual physician referrals for the most recent 12-month period immediately preceding the date of the application. The referrals will be verified with data maintained by the Department through its "Annual Hospital Statistical Survey" and/or "Annual Freestanding Statistical Survey." Further, the use of referrals from an existing facility cannot drop the facility below the minimum volume requirement.
- Added geographic boundaries for referral commitments (75-mile radius for rural and micropolitan statistical area counties and 20-mile radius for metropolitan statistical area counties).
- Added language that would establish a Pilot Program to implement hospital-based portable CT scanners into a limited number of facilities. The requirements include certification as a Level I or Level II Trauma Facility by the American College of Surgeons. Qualified facilities could obtain up to two scanners of their choice. The scanner(s) would not be subject to minimum volume requirements and would not generate volume data for future CON applications. Data would be collected by the Department regarding utilization, cost, and benefit for patient care as compared to full body CT scanners.
- Added language that provides for expansion, replacement, relocation and acquisition of Dental CT scanners. The recommended volume threshold for expansion is 300 dental examinations per year. The recommended volume threshold for replacement, relocation, and acquisition is 200 dental examinations per year.
- Added language that would establish criteria for a dedicated Pediatric CT scanner.
- Added a .25 conversion factor for pediatric patients to the existing weights for the calculation of CT volume data to recognize the increased time and effort in imaging the pediatric patient in non-pediatric CT scanners.
- Added language to clarify the definition of a “billable procedure” by adding that the CT procedure(s) be “performed in Michigan.”
- Added an additional exclusion to the definition of a “CT scanner” for clarification purposes: “CT simulators used solely for treatment planning purposes in conjunction with an MRT unit.”
- Other technical changes for clarity and consistency with the other CON Review Standards.

A second set of revisions to the CON Review Standards for CT Scanner Services received final approval by the CON Commission on April 30, 2008 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 June 20, 2008. The final language change includes an exemption for non-diagnostic intraoperative guidance tomographic units (such as the O-arm) from the definition of “CT Scanner.”

The revisions to the CON Review Standards for MRI Services received final approval by the CON Commission on September 18, 2007 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, 2007.

The proposed language changes allow for a fixed MRI unit, after converting from mobile to fixed, to be placed at the applicant's current, approved host site or at the applicant's licensed hospital site as defined in the standards. In addition, the proposed changes include technical changes to assist with the CON on-line application system.

The revisions to the CON Review Standards for MRT Services/Units received final approval by the CON Commission on April 30, 2008 and were forwarded to the Governor and legislature. The Governor took negative action within the 45 days; therefore, the revisions did not become effective. The final language changes would have included the following:

- A definition for proton beam therapy (PBT) for purposes of Section 10.
- Additional language to provide requirements to initiate an MRT service providing proton beam therapy.
- An update of the following project delivery requirement 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.

The revisions to the CON Review Standards for NICU Services/Beds received final approval by the CON Commission on September 18, 2007 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, 2007. The final language changes include, but are not limited to, the following:

- Modified the project delivery requirements in Section 11(1)(c)(ix) and (x) to require pediatric specialties.
- Other technical changes.

The revisions to the CON Review Standards for NH-HLTCU Beds received final approval by the CON Commission on March 11, 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 June 2, 2008 as specified in the proposed final action. The final language changes include, but are not limited to, the following:

- Added quality measures that apply to the applicant facility and all NH-HLTCU under common ownership or control both in Michigan and out-of-state. Common ownership would look at out-of-state nursing homes only when an applicant has less than 10 Michigan nursing homes. Thus, if the applicant has 10 or more Michigan nursing homes, then only Michigan homes will be evaluated for the quality measures. The total number of facilities, which meet the quality measures could not exceed 14% or up to 5 of its facilities. The quality measures criteria apply differently depending on the CON activity. The measures are as follows:

- A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- Termination of a medical assistance provider enrollment and trading partner agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.
- A number of citations at level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.
- Criteria that look for facilities that are listed as a special focus Nursing Home by the Center for Medicare and Medicaid Services.
- Outstanding debt obligation to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP).

- When a home with quality issues is acquired, it must participate in a quality improvement program, such as My Innerview, Advancing Excellence, or another comparable program for five years and provide an annual report to the Michigan State Long-Term-Care Ombudsman, Bureau of Health System, and the annual report shall be posted in the facility being acquired.
- Elimination of Alzheimer's Disease (384 beds), Health Needs for Skilled Nursing Care (HNSNC) (173 beds), and Religious (292 beds) from the Addendum for Special population Groups. These categories will no longer be eligible for additional beds. However, the current programs can be acquired, but if a facility de-licenses any of the beds, the beds will be removed from the pool.
- Modification of the high occupancy criteria at 6(1)(d)(ii) by modifying the facility criteria to 97% average occupancy for 12 quarters and eliminating the planning area requirement.
- Added a rural high occupancy provision given the recommendation for removal of HNSNC beds with the following criteria:
  - The planning area must have a population density of less than 28 individuals per square mile.
  - The facility must have an average occupancy rate of 92% for the most recent 24 months.
- Hospice (130 beds) and Ventilator Dependent (179 beds) will be maintained with modified criteria.
- Behavioral Patients (400 beds) and Traumatic Brain Injury/Spinal Cord Injury Patients (400 beds) are proposed to be added to the addendum.
- Added the New Design Model as regular criteria within the Standards.

- Added language that would allow for relocation of beds within the planning area from an existing nursing home/HLTCU to another existing nursing home/HLTCU no more than once every 7 years, and no more than 50% of the beds could be relocated from the transferring facility to the receiving facility. The quality measures criteria will apply to the receiving facility.
- Added language that requires the Department to recalculate the use rate and the bed need on a biennial basis utilizing the most recent data available.
- The comparative review criteria has been reviewed and modified to include the following:
    - Percentage of Medicaid days during the most recent 12 months.
    - Percentage of Medicaid licensed beds at the facility during the most recent 12 months.
    - Percentage of Medicare participation during the most recent 12 months.
    - Deduction of points for non-renewal or revocation of license and non-renewal or termination of Medicaid or Medicare certification.
    - Participation in a culture change model.
    - Percentage of applicant's cash.
    - Facility which is fully equipped with sprinklers.
    - Percentage of private rooms.
- Inclusion of clarifying language with the use of "adjacent private changing room" in Section 10(8).
- Other technical changes.

A second set of revisions to the CON Review Standards for NH-HLTCU Beds received final approval by the CON Commission on April 30, 2008 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 June 20, 2008. The final language change exempts HLTCUs from the recently approved 50% limitation for relocation of beds within a planning area from an existing HLTCU to another NH/HLTCU.

The revisions to the CON Review Standards for OHS Services received final approval by the CON Commission on December 11, 2007 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 25, 2008. The final language changes include, but are not limited to, the following:

- Facilities providing open heart surgery services in Michigan are required to participate in the Society of Thoracic Surgeons (STS) database and the program's state-wide auditing.
- Updated Major ICD-9-CM Code Groups and weights.
- Replaced the word "procedure" wherever it appeared in the standards with "cases" for count purposes, as any given case could possibly involve multiple procedures.
- Each physician credentialed by an applicant hospital to perform adult open heart surgery cases, as the attending physician, shall perform a minimum of 75 adult open heart surgery cases per year; this is a revision from 50 adult open heart cases per year.
- Consulting hospitals to be required to perform a minimum of 400 cases per year for at least three consecutive years. This is an increase from the current 350 requirement.

- Once MIDB data has been committed to support a CON application for open heart surgery services, it shall not be recommitted. After seven years, only the incremental increase in MIDB data could be committed to support a CON application for open heart surgery services.
- Clarified the definitions of adult and pediatric open heart surgery.
- Revised the methodology to utilize separate weights for both principal and non-principal diagnostic codes, uses data from hospitals that currently have OHS programs, and incorporates all available procedure codes ("any mention") within each diagnostic code. The weights will be recalculated every three years.
- Other technical changes.

The revisions to the CON Review Standards for Psychiatric Beds and Services received final approval by the CON Commission on December 11, 2007 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 25, 2008. The final language changes include, but are not limited to, the following:

- Bed Need Methodology will be maintained and calculated every two years to determine overall planning area need with an adjustment for low occupancy facilities.
- Modified the adult planning areas from the Community Mental Heath boundaries to health service area (HSA) boundaries.
- Modified the minimum annual average occupancy rate within the project delivery requirements for adult beds from 85% to 60%. If a facility's average occupancy falls below 60%, the facility must decrease the number of beds, not to be less than 10 beds, to bring its annual average occupancy to 60%.
- Modified the minimum annual average occupancy rate within the project delivery requirements for child/adolescent beds from 75% to 40%. If a facility's average occupancy falls below 40%, the facility must decrease the number of beds, not to be less than 10 beds, to bring its annual average occupancy to 40%.
- Added a high occupancy provision that will allow expansion outside of the bed need for a facility as follows:
    - Facilities with 19 beds or less with an average occupancy rate of 75% for previous two years
    - Facilities with 20 beds or more with an average occupancy rate of 80% for previous two years
    - The number of beds that a facility would be eligible for is based on the following formula: the average daily census multiplied by 1.5 for adult beds and 1.7 for child/adolescent beds.
- Increased replacement zone to 15 miles within a planning area.
- Minimum number of beds in a psychiatric unit will be 10 beds. This will allow Critical Access Hospitals to initiate a unit.
- The 1 bed for 20 bed rule will be changed to 1 bed for 10 bed rule if the bed need is 9 beds or less in the planning area.
- To increase beds at a facility utilizing beds in the inventory, the facility shall be at 70% average occupancy for the previous two years.
- Other technical changes and updates.

The revisions to the CON Review Standards for Surgical Services received final approval by the CON Commission on April 30, 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 June 20, 2008. The final language changes include, but are not limited to, the following:

- Added language under Section 7 that would exempt an existing service with one or two operating rooms which is located in a rural or micropolitan statistical area county from the volume requirements.
- Clarified language under Section 11, Documentation of Projections.
- Other technical changes.

The revisions to the CON Review Standards for UESWL Services/Units received final approval by the CON Commission on December 11, 2007 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 25, 2008. The final language changes include, but are not limited to, the following:

- Added language to allow for acquisition of a unit(s) or a service.
- Added language to allow for relocation of a unit(s) or a service.
- Developed separate definitions for replace and upgrade.
- Clarified language to reflect that only MIDB data can be used for projections for initiation.
- Added language for initiation of a mobile UESWL service to require that 100 UESWL procedures must be projected in each region in which the proposed mobile service is proposing to operate.
- Eliminated comprehensive kidney stone treatment center (CKSTC) and all references as it is no longer needed.
- Other technical changes.

CERTIFICATE OF NEED COMMISSIONERS

Norma Hagenow, CON Chairperson (10/1/07 – 3/11/08), Vice-Chairperson (Eff. 3/12/08)
Edward B. Goldman, CON Vice-Chairperson (10/1/07 – 3/11/08), Chairperson (Eff. 3/12/08)
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Adam A. Miller
Michael A. Sandler, MD
Vicky Schroeder (Eff. 4/9/08, replaced Kathie A. VanderPloeg-Hoekstra)
Thomas M. Smith
Kathie A. VanderPloeg-Hoekstra (appointment expired 4/9/08 and resigned effective 4/9/08)
Michael W. Young, DO

For a list and contact information of the current CON Commissioners, please visit our web site at **www.michigan.gov/con**.