

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED PROGRAM

ANNUAL ACTIVITY REPORT

**October 2006 through September 2007
(FY2007)**

**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 19th report to the Commission and covers the period beginning October 1, 2006 through September 30, 2007 ("FY2007"). 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 The law was repealed in 1986. Michigan's law was not repealed and, during the 1980s, it became evident that the expectations and decisions of Michigan's CON program were unclear and unpredictable to many applicants.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 FY2007, the Program Review Section continued work to develop 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 module for substantive applications is scheduled for release in December 2007. Potential comparative applications will not be part of the online system until further refinements are made.

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 FY2007, there were 170 applications for nonsubstantive review, 135 for substantive individual review and 15 for comparative review, for a total of 320 applications received. Twenty (20) 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 FY2007, 319 applications for CON review were approved, including five (5) emergency CON approvals. Fifty-eight (58) 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 FY2007.

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 FY2007, the Section’s financial analyst reviewed approximately 8 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					
FY2003 - FY2007					
	FY2003	FY2004	FY2005	FY2006	FY2007
LOIs Received	464	608	536	562	582
Processed within 15 Days	N/A	N/A	532	548	579

Note: FY2002-04 not available. Tracking system to measure compliance for this Rule developed in 2005.

In FY2007, 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 FY2006*	
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 FY2003 - FY2007					
	FY2003	FY2004	FY2005	FY2006	FY2007
Nonsubstantive	90	101	127	162	170
Substantive Individual	188	237	162	212	135
Comparative	2	10	13	9	15
TOTALS	280	348	302	383	320

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 - FY2007

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

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
FY2003 - FY2007

ALL APPLICATIONS	FY2003	FY2004	FY2005	FY2006	FY2007
Complete	105	110	38	18	72
Incomplete	175	238	264	365	248
Percent Incomplete	63%	68%	87%	95%	78%

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
FY2003 - FY2007

	FY2003	FY2004	FY2005	FY2006	FY2007
Nonsubstantive	39	40	35	35	37
Substantive Individual	116	117	112	109	126
Comparative	149	169	146	108	132

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 - FY2007						
	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

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 FY2003 - FY2007					
	Approved	Approved w/ Conditions	Disapproved	Percent Disapproved	TOTAL
FY2003	213	24	8	5%	245
FY2004	211	82	17	5%	310
FY2005	199	88	5	2%	292
FY2006	213	126	4	1%	343
FY2007	263	60	10	3%	333

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					
FY2003 - FY2007					
	FY2003	FY2004	FY2005	FY2006	FY2007
Applications Submitted	280	348	302	383	320
Final Decisions	250	308	294	345	319

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.

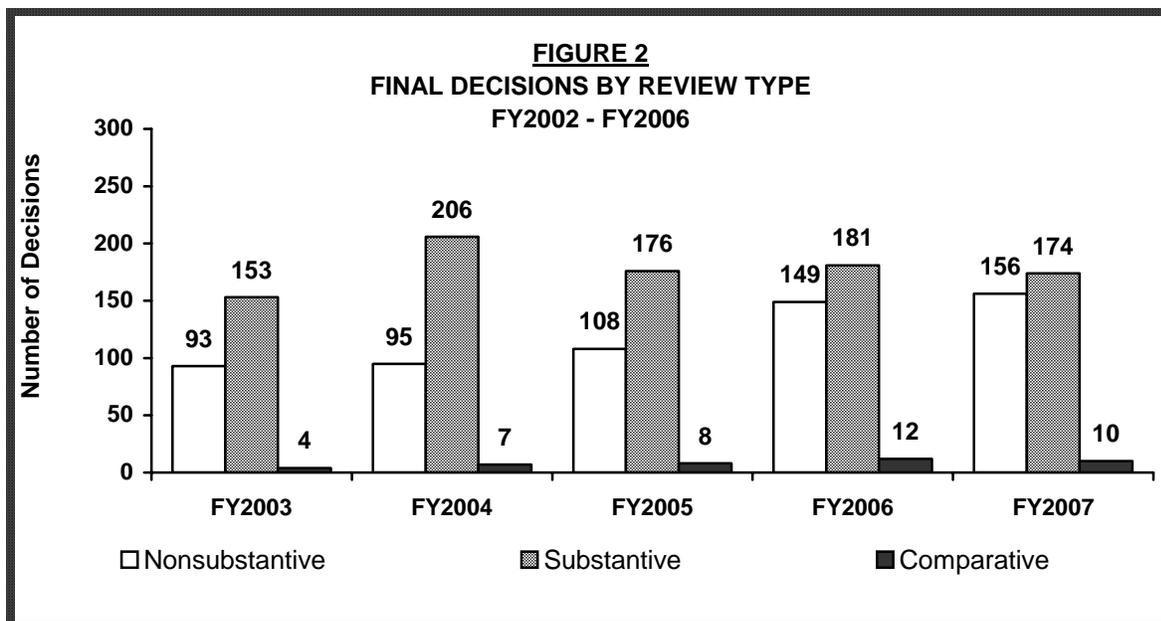


Table 9 summarizes final decisions by review categories defined in MCL 333.22209(1) and as summarized below:

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 2007, the covered capital expenditure threshold was \$2,817,500. The threshold is updated every January in accordance with Part 222.

TABLE 9					
FINAL DECISIONS ACTIVITY CATEGORY					
FY2003 - FY2007					
Approved	FY2003	FY2004	FY2005	FY2006	FY2007
Acquire, Begin, or Replace a Health Facility	41	75	54	57	51
Change in Bed Capacity	23	29	18	26	29
Covered Clinical Services	209	211	222	255	237
Covered Capital Expenditures	36	30	23	33	30
Disapproved					
Acquire, Begin, or Replace a Health Facility	1	2	1	2	2
Change in Bed Capacity	1	2	2	0	1
Covered Clinical Services	0	3	3	2	1
Covered Capital Expenditures	0	1	1	0	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 FY2003 - FY2007				
	Approved	Approved With Conditions	Disapproved	TOTALS
Number of Final Decisions				
FY2003	240	25	3	268
FY2004	221	81	6	308
FY2005	200	88	6	294
FY2006	234	106	3	345
FY2007	257	58	4	319
Total Project Costs				
FY2003	\$992,397,822	\$77,078,656	\$700,000	\$1,070,176,478
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

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 FY2003 - FY2007					
	FY2003	FY2004	FY2005	FY2006	FY2007
Emergency CONs Issued	2	1	9	3	5
Issued within 10 working days	N/A	N/A	9	3	5

Note: FY2001-04 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					
FY2003 - FY2007					
	FY2003	FY2004	FY2005	FY2006	FY2007
Amendments Received	41	70	97	77	61
Amendment Decisions Issued	N/A	N/A	77	97	61
Issued within required time frame	N/A	N/A	54	84	60

Note: FY2002-04 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 FY2003 - FY2007					
	Number of Applications	% Change From Previous Year	Total Project Costs	% Change From Previous Year	
Letters of Intent Submitted					
FY2003	464	4%	\$2,065,537,808	50%	
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%	
Applications Submitted					
FY2003	280	22%	\$1,224,524,464	14%	
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%	
Final Decisions Issued					
FY2003	270	21%	\$1,070,176,478	1%	
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%)	

COMPLIANCE ACTIONS

There were 310 projects requiring follow-up for FY2007 based on the Department's Monthly Follow-up/Monitoring Report as shown in **Table 14**.

TABLE 14 FOLLOW UP AND COMPLIANCE ACTIONS FY2002 - FY2006					
	FY2003	FY2004	FY2005	FY2006	FY2007
Projects Requiring Follow-up	327	301	298	310	413
Compliance Orders Issued	2	1	2	0	2

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 FY2003 - FY2007					
CON Fee	FY2003	FY2004	FY2005	FY2006	FY2007
\$ 0*	5	5	10	4	6
\$1,500	N/A	N/A	54	84	75
\$5,500	N/A	N/A	119	191	141
\$8,500	N/A	N/A	48	104	98
TOTALS	280	348	302	383	320

* 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 FY2003 – FY2007					
	FY2003	FY2004	FY2005	FY2006	FY2007
Program Cost	\$1,482,828	\$1,274,306	\$1,287,315	\$1,877,110	\$1,665,800
Application Fees	\$776,460	\$951,146	\$1,331,409	\$1,884,894	\$1,666,500
Fees % of Costs	52%	75%	100%+	100%+	100%+

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 FY2007 indicates the CON program is in compliance with Section 22215(6).

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY2007, the Certificate of Need Commission revised the review standards for Bone Marrow Transplantation (BMT) Services, Computed Tomography (CT) Scanner Services, Hospital Beds, Magnetic Resonance Imaging (MRI) Services, and Positron Emission tomography (PET) Scanner Services.

The revisions to the CON Review Standards for BMT Services received final approval by the CON Commission on December 12, 2006 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 8, 2007. The final language changes included, but are not limited to, the following:

- “On-site” availability of services to include “or physically connected.”
- Minimum volume requirements for an “existing BMT service” with which a proposed new BMT program must enter into a “consulting agreement”: Replaced the minimum volume requirement with Foundation for the Accreditation of Cell Therapy (FACT) accreditation.

The revisions to the CON Review Standards for CT Scanner Services received final approval by the CON Commission on September 19, 2006 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 December 27, 2006. The final language changes included, but are not limited to, the following:

- Using 200 dental CT images for an initiation number, based upon dental procedures performed in preceding 12-month period.
- Using 200 CT equivalents for maintenance number after initiation, and annually thereafter.
- Demonstration of training and/or certification of dentists and dental CT operators.
- Adding a research exemption language section for dental CT research applications such that someone who wanted to acquire a machine for 100% research would not be required to meet initiation and maintenance volume numbers.

The revisions to the CON Review Standards for Hospital Beds received final approval by the CON Commission on December 12, 2006 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 8, 2007. The final language changes included, but are not limited to, the following:

- Changes to the high occupancy language which includes a 10% factor for pediatrics and obstetrics beds because those beds cannot easily accommodate other patients, 80% occupancy for the previous, consecutive 24 months based on licensed and approved beds for all hospitals, and a project delivery requirement that requires an achievement of a minimum occupancy of 75% over the last 12-month period in the three years after the new beds are put into operation, and for each subsequent calendar year, or the number of new licensed beds shall be reduced to achieve a minimum of 75% average annual occupancy for the revised licensed bed complement.
- Expanded comparative review requirements for applications subject to comparative review other than limited access areas which have their own comparative review criteria. A maximum of 25 pts will be awarded for uncompensated care volume, 20 pts for

Medicaid volume, 25 pts for impact on inpatient capacity [closure of hospital(s)], and 30 pts for percentage of market share.

The revisions to the CON Review Standards for MRI Services received final approval by the CON Commission on December 12, 2006 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 8, 2007. The final language changes included, but are not limited to, the following:

- Added definition and weight of .25 for a “special needs patient.”
- Changed the relocation zone from a 5-mile radius to a 10-mile radius for metropolitan statistical area counties.
- Clarified language regarding relocation of an MRI unit vs. service.
- Changed \$500,000 to \$750,000 under Section 2(1)(uu) for “upgrade an existing MRI” and under Section 2(1)(oo) for “replace an existing MRI unit” definitions.
- Added a definition and weight for a “re-sedated patient.”
- Updated Section 12(1)(c)(vii)(C) to allow for an MRI technologist to be registered by either the American Registry of Radiologic Technicians or the American Registry of Magnetic Resonance Imaging Technologists (ARMRIT).
- Added requirement for expansion of a dedicated pediatric MRI service: the existing dedicated pediatric MRI units must be meeting the minimum volume requirement for maintenance, which is 3,500 adjusted procedures per unit.

The revisions to the CON Review Standards for PET Scanner Services received final approval by the CON Commission on December 12, 2006 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 8, 2007. The final language changes included, but are not limited to, the following:

- Requirements for conversion from mobile to fixed PET services.
- Utilizing fixed PET scans to expand to a mobile service instead of initiating a mobile PET service.
- Language that allows a “free” replacement of the current PET scanner to a PET/CT scanner.
- Language to allow for relocation of a unit or service.
- Requirements for a dedicated pediatric PET scanner.
- PET equivalents updated.
- Elimination of 85/15 rule [where at least 85 percent of the data was from a single planning area in which 85 percent of the proposed mobile PET service (patient visits) would be provided] for mobile PET scanner services.
- Commitment of data for a given PET unit reduced from lifetime to five years.

CERTIFICATE OF NEED COMMISSIONERS

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Edward B. Goldman, CON Vice-Chairperson
Peter Ajluni, DO
Roger G. Andrzejewski (appointment expired 4/9/07 and resigned effective 4/9/07)
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