MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED PROGRAM

ANNUAL ACTIVITY REPORT

October 2009 through September 2010
(FY2010)

Michigan Department of Community Health

MDCH

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http://www.michigan.gov/con

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TABLE OF CONTENTS

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 22nd report to the Commission and covers the period beginning October 1, 2009 through September 30, 2010 ("FY 2010"). Data contained in this report may differ from prior reports due to updates subsequent to each report's publishing date.

Administration

The Department through its Health 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 a SAC to assist in the development of proposed CON review standards, which consists of a 2/3 majority of experts in the subject area. Further, the Commission, if determined necessary, may submit a request to the Department to engage the services of consultants or request the Department to contract with an organization for professional and technical assistance and advice or other services to assist the Commission in carrying out its duties and functions.

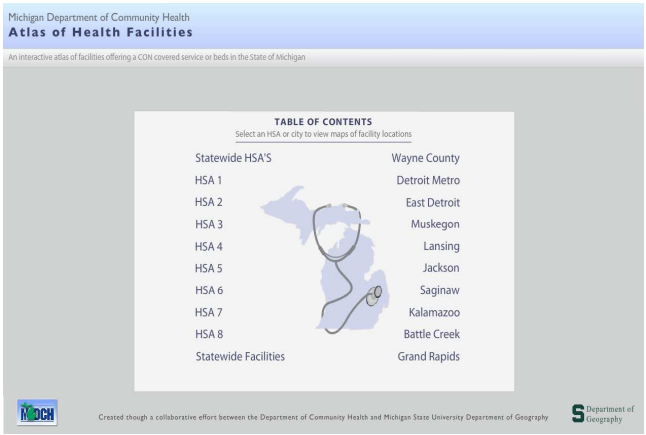
The Department through its Evaluation Section manages and reviews all incoming letters of intent, applications and amendments. These functions include determining if a CON is required for a proposed project as well as providing the necessary application materials when applicable. In addition, the Section is responsible for monitoring implementation of approved projects as well as the long term compliance with the terms and conditions of approvals.

During FY 2010, the Evaluation Section continued its work to move the program into the digital age. Staff continued to improve the online application and management information system (CON e-Serve). The first module was released in 2006. Today, the vast majority of Letters of Intent, CON applications, and amendments are filed online. The Michigan CON program is still the only program nationally to have an online application system.

In April 2008, the Section released its first Michigan Atlas of Licensed Health Facilities in collaboration with the Michigan State University Department of Geography. This fiscal year the Atlas was transformed to a dynamic web-based mapping system that allows users to select various types of facilities as well as select individual facilities to see the types of covered services offered and the facilities most recent utilization data from the annual CON survey of approved facilities.

The utilization data comes from a new online survey system developed in collaboration with the Southeastern Michigan Health Association. This online system has greatly reduced the amount of department staff time necessary to collect annual utilization data from approved facilities while assuring timely data to the Commission for policy and standards development.

These three initiative have greatly increased the availability of CON related information and data to improve and streamline the review process, better inform policy makers, and enhance community knowledge about Michigan's health care system.



http://health.geo.msu.edu/atlas.html

CON Required

In accordance with MCL 333.22209, a person or entity is required to obtain a certificate of need, unless elsewhere specified in Part 222, for any of the following activities:

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

CON Application Process

To apply for a CON, the following steps must be completed:

- Letter of Intent filed and processed prior to submission of an application,
- CON application filed on appropriate date as defined in the CON Administrative Rules,
- Application reviewed by the Evaluation Section,
- Issuance of Proposed Decision by the Bureau of Legal and Policy Affairs,
  - Appeal if applicant disagrees with the Proposed Decision issued,
- Issuance of the Final Decision by the MDCH Director.

There are three types of CON review: nonsubstantive, substantive individual, and comparative. The Administrative Rules for the CON program establish time lines by which the Department must issue a proposed decision on each CON application. The proposed decision for a nonsubstantive review must be issued within 45 days of the date the review cycle begins, 120 days for substantive individual, and 150 days for comparative reviews.

FY 2010 in Review

In FY 2010, there were 435 Letters of Intent received resulting in 303 applications filed for CON review and approval, including four (4) emergency applications. In addition, the Department received 85 amendments to previously approved applications. In total, the Department approved 254 proposed projects resulting in approximately $795,886,286 of new capital expenditures into Michigan's healthcare system.

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

The CON Commission also reviewed and revised seven (7) different Review Standards: Air Ambulance Services; Bone Marrow Transplantation Services; Heart, Lung, and Liver Transplantation Services; Magnetic Resonance Imaging Services; Neonatal Intensive Care Unit Services; Pancreas Transplantation Services; and Psychiatric Beds and Services.

Report

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

HISTORICAL OVERVIEW OF MICHIGAN'S CERTIFICATE OF NEED PROGRAM

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

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

1988 The goal of the program is to balance cost, quality, and access issues and ensure that only needed services are developed in Michigan. However, the program's ability to meet these goals was significantly diluted by the fact that most application denials were overturned in the courts. In order to address this, Michigan's CON Reform Act of 1988 was passed to develop a clear, systematic standards development process and reduce the number of services requiring a CON.

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

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

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

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

Present The CON program is now more predictable so that applicants 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

Commission The Commission is an 11-member body. The Commission, appointed by the Governor and confirmed by the Senate, is responsible for approving CON review standards used by the Department to make decisions on individual CON applications. The Commission also has the authority to revise the list of covered clinical services subject to CON review. Appendix I is a list of the CON commissioners for FY2010.

NEWTAC The New Technology Advisory Committee is a standing committee responsible for advising the Commission on the new technologies, including medical equipment and services that have not yet been approved by the federal Food and Drug Administration for commercial use.

SAC Standards Advisory Committees ("SAC") may be appointed by and report to the CON Commission. The SACs advise the Commission regarding creation of, or revisions to, the standards. The committees are composed of a 2/3 majority of experts in the subject matter and include representatives of organizations of health-care providers, professionals, purchasers, consumers, and payers.

MDCH The Michigan Department of Community Health is responsible for administering the CON program and providing staffing support for the Commission. This includes promulgating applicable rules, processing and rendering decisions on applications, and monitoring and enforcing the terms and conditions of approval. These functions are within the Bureau of Legal and Policy Affairs.

Policy Section The Policy Section within the Bureau provides professional and support staff assistance to the Commission and its committees in the development of new and revised standards. Staff support includes researching issues related to specific standards, preparing draft standards, and performing functions related to both Commission and committee meetings.

Evaluation Section The Evaluation Section also within the Bureau has operational responsibility for the program, including providing assistance to applicants prior to and throughout the CON process. The section is responsible for reviewing all Letters of Intent and applications as prescribed by the Administrative Rules. Staff determines if a proposed project requires a CON. If a CON is required, staff identifies the appropriate application forms for completion by the applicant and submission to the Department. The application review process includes the assessment of each application for compliance with all applicable statutory requirements and CON Review Standards, and preparation of a Program and Finance report documenting the analysis and findings. These findings are used by the Director to make a final decision to approve or deny a project.

In addition to the application reviews, the Section reviews requests for amendments to approved CONs as allowed by the Rules. Amendment requests involve a variety of circumstances, including changes in how an approved project is financed and authorization for cost overruns. The Section is also responsible for monitoring the implementation of approved projects as well as the long-term compliance with the terms and conditions of approvals.

The Section also provides the Michigan Finance Authority ("MFA") information when healthcare entities request financing through MFA bond issues and Hospital Equipment Loan Program ("HELP") loans. This involves advising on whether a CON is required for the item(s) that will be bond financed.

CERTIFICATE OF NEED PROCESS

The following discussion briefly describes the steps an applicant follows in order to apply for a Certificate of Need.

Letter of Intent — An applicant must file an LOI with the Department and, if applicable, the regional CON review agency. The CON Evaluation Section identifies for an applicant all the necessary application forms required based on the information contained in the LOI.

Application — An applicant files on or before the designated application date an application with the Department and, if applicable, the regional review agency. The Evaluation Section reviews an application to determine if it is complete. If not complete, additional information is requested. The review cycle starts after an application is deemed complete or received in accordance with the Administrative Rules.

Review Types and Time Frames — There are three review types: nonsubstantive, substantive individual and comparative. Nonsubstantive reviews that involve projects such as replacement of covered equipment or changes in ownership that do not require a full review. Substantive individual reviews involve projects that require a full review but are not subject to comparative review as specified in the applicable CON Review Standards. Comparative reviews involve situations where two or more applicants are competing for a resource limited by a CON Review Standard, such as hospital and nursing home beds. The maximum review time frames for each review type, from the date an application is deemed complete or received until a proposed decision is issued, are: 45 days for nonsubstantive, 120 for substantive individual and 150 days for comparative reviews. The comparative review time frame includes an additional 30-day period for determining if a comparative review is necessary. Whenever this determination is made, the review cycle begins for comparative reviews.

Review Process — The Evaluation Section reviews the application. Each application is reviewed separately unless part of a comparative review. Each application review includes a program and finance report documenting the Department's analysis and findings of compliance with the statutory review criteria, as set forth in Section 22225 of the CON law and the applicable CON Review Standards.

Proposed Decision — The Bureau of Legal and Policy Affairs in which the Evaluation Section resides issues a proposed decision to the applicant within the required time frame. This decision is binding unless reversed by the Department Director or appealed by the applicant. The applicant must file an appeal within 15 days of receipt of the proposed decision if the applicant disagrees with the proposed decision or its terms and conditions. In the case of a comparative review, a single decision is issued for all applications in the same comparative group.

Final Decision — If the proposed decision is not appealed, a final decision is made by the Director of the Department of Community Health in accordance with MCL 333.22231. If a hearing on the proposed decision is requested, the final decision by the Director is not issued until completion of the hearing and any filing of exceptions to the proposed decision by the Administrative Tribunal. A final decision by the Director may be appealed to the applicable circuit court.

LETTERS OF INTENT

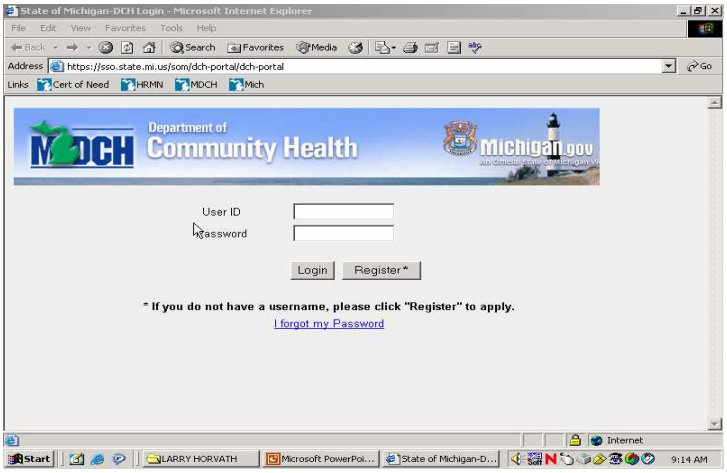
The CON Administrative Rules, specifically Rule 9201, provides that Letters of Intent ("LOIs") must be processed within 15 days of receipt. Processing an LOI includes entering data in the program's management information system, verifying proof of documentation to do business in Michigan and ownership, 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
FY2006 - FY2010

	LOIs Received	Processed within 15 Days	Percent Processed within 15 Days
FY2006	562	548	98%
FY2007	582	579	99%
FY2008	521	517	99%
FY2009	335	333	99%
FY2010	435	435	100%

In FY 2010, all LOIs were processed in a timely manner as required by Rule and available for public viewing on the online application system. The online system allows for quicker receipt and processing of LOIs and subsequent applications by the Evaluation Section, as well as modifying these applications by applicants when needed.



In 2006, Michigan became the first state to have an online application and information system. Today 100% of all Letters of Intent and more than 95% of all applications are submitted on-line.

TYPES OF CERTIFICATE OF NEED APPLICATION REVIEWS

The Administrative Rules also establish three types of project reviews: nonsubstantive, substantive, and comparative. The Rules specify the time frames by which the Bureau must issue its proposed decision related to a CON application. The time allowed varies based on the type of review.

Nonsubstantive

Nonsubstantive reviews involve projects that are subject to CON review but do not warrant a full review. The following describes potentially eligible for type of projects for nonsubstantive review:

- Acquire an existing health facility;
- Replace a health facility within the replacement zone and below the covered capital expenditure;

- Add a host site to an existing mobile network/route that does not require data commitments;
- Replace or upgrade a covered clinical equipment; or
- Acquire or relocate an existing freestanding covered clinical service.

The Rules allow the Bureau up to 45 days from the date an application is deemed complete to issue a proposed decision. Reviewing these types of proposed projects on a nonsubstantive basis allows an applicant to receive a decision in a timely fashion while still being required to meet current CON requirements, including quality assurance standards.

Substantive Individual

Substantive individual review projects require a full review but are not subject to comparative review and not eligible for nonsubstantive review. An example of a project reviewed on a substantive individual basis is the initiation of a covered clinical service such as computed tomography (CT) scanner services. The Bureau must issue its proposed decision within 120 days of the date a substantive individual application is deemed complete or received.

Comparative

Comparative reviews involve situations where two or more applications are competing for a limited resource such as hospital or nursing home beds. A proposed decision for a comparative review project must be issued by the Bureau no later than 120 days after the review cycle begins. The cycle begins when the determination is made that the project requires comparative review. According to the Rules, the Department has the additional 30 days to determine if, in aggregate, all of the applications submitted on a window date exceed the current need. A comparative window date is one of the three dates during the year on which projects subject to comparative review must be filed. Those dates are the first working day of February, June, and October.

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

Figure 1 delineates services/beds subject to comparative review.

*FIGURE 1: Services/Beds Subject to Comparative Review in FY2010**	
Neonatal Intensive Care	Nursing Home Beds for Special Population Groups
Hospital Beds	Psychiatric Beds
Hospital Beds (HIV)	Transplantations (excluding Pancreas)
Nursing Home Beds	

Note: See individual CON Review Standards for more information.

Table 2 shows the number of applications received by the Department by review type.

TABLE 2
APPLICATIONS RECEIVED BY REVIEW TYPE
FY2006 - FY2010

	FY2006	FY2007	FY2008	FY2009	FY2010
Nonsubstantive	162	170	183	115	144
Substantive Individual	212	135	165	78	131
Comparative	9	15	37	26	22
TOTALS	383	320	385	219	297

Note: Does not include emergency CON or swing bed applications.

Table 3 provides a summary of applications received and processed in accordance with Rule 9201. The Rule requires the Evaluation Section to determine if additional information is needed within 15 days of receipt of an application. Processing of applications includes: updating the management information system, verifying submission of required forms, and determining if other information is needed in response to applicable Statutes and Standards.

TABLE 3
APPLICATIONS RECEIVED AND PROCESSED WITHIN 15 DAYS
FY2006 - FY2010

	FY2006	FY2007	FY2008	FY2009	FY2010
Applications Received*	383	320	388	220	303
Processed within 15 Days	383	320	387	219	303
Percent Processed within 15 Days	100%	100%	100%	100%	100%

Note: Includes emergency CON and swing bed applications.

Table 4 provides an overview of the average number of days taken by the Evaluation Section to complete reviews by type.

TABLE 4
AVERAGE NUMBER OF DAYS IN REVIEW CYCLE BY REVIEW TYPE
FY2006- FY2010

	FY2006	FY2007	FY2008	FY2009	FY2010
Nonsubstantive	35	37	40	38	37
Substantive Individual	109	126	116	113	113
Comparative	108	132	151	260*	153

Note: Average review cycle accounts for extensions requested by applicants.

- In FY 2009, the average days for comparative review applications increased substantially due to multiple revisions to the nursing homes review standards.

EMERGENCY CERTIFICATES OF NEED

Table 5 shows the number of emergency CONs issued. The Department is authorized by Section 22235 of the Public Health Code to issue emergency CONs when applicable. Rule 9227 permits up to 10 working days to determine if an emergency application is eligible for review under Section 22235. Although it is not required by Statute, the Bureau attempts to issue emergency CON decision to the Director for final review and approval within 10 days from receipt of request.

TABLE 5
EMERGENCY CON DECISIONS ISSUED
FY2006 - FY2010

	FY2006	FY2007	FY2008	FY2009	FY2010
Emergency CONs Issued	3	5	3	1	4
Percent Issued within 10 Working Days	100%	100%	67%	100%	100%

PROPOSED DECISIONS

Part 222 establishes a 2-step decision making process for CON applications that includes both a proposed decision and final decision. After an application is deemed complete and reviewed by the Evaluation Section, a proposed decision is issued by the Bureau to the applicant and the Department Director according to the time frames established in the Rules.

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

TABLE 6
PROPOSED DECISIONS ISSUED
FY2006- FY2010

	Nonsubstantive		Substantive		Comparative	
	Issued	Within 45 days	Issued	Within 120 days	Issued	Within 150 days
FY2006	162	100%	175	99%	3	100%
FY2007	152	99%	162	98%	15	100%
FY2008	176	99%	145	99%	6	50%
FY2009	130	100%	114	99%	20	90%
FY2010	123	99%	103	100%	17	100%

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

TABLE 7
COMPARISON OF PROPOSED DECISIONS BY DECISION TYPE
FY2006- FY2010

	Approved	Approved w/ Conditions	Disapproved	Percent Disapproved	TOTAL
FY2006	213	126	4	1%	343
FY2007	263	60	10	3%	333
FY2008	282	50	5	2%	337
FY2009	240	25	19	7%	284
FY2010	212	27	7	3%	246

Note: Not all proposed decisions issued in a given year will have a final decision in the same year.

If a proposed decision is disapproved, an applicant may request an administrative hearing that suspends the time frame for issuing a final decision. After a proposed disapproval is issued, an applicant may also request that the Department consider new information. The Administrative Rules allow an applicant to submit new information in response to the areas of noncompliance identified by the Department's analysis of an application and the applicable statutory requirements to satisfy the requirements for approval.

FINAL DECISIONS

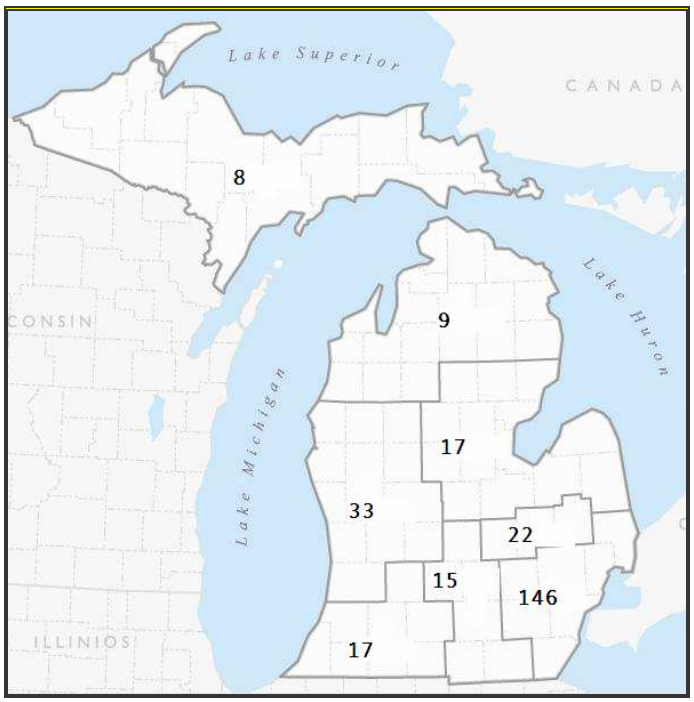
The Director issues a final decision on a CON application following either a proposed decision or the completion of a hearing, if requested, on a proposed decision. Pursuant to Section 22231(1) of the Public Health Code, the Director may issue a decision to approve an application, disapprove an application, or approve an application with conditions or stipulations. If an application is approved with conditions, the conditions must be explicit and relate to the proposed project. In addition, the conditions must specify a time period within which the conditions shall be met, and that time period cannot exceed one year after the date the decision is rendered. If approved with stipulations, the requirements must be germane to the proposed project and agreed to by the applicant.

This section of the report provides a series of tables summarizing final decisions for each of the review thresholds for which a CON is required. It should be noted that some tables will not equal other tables, as many applications fall into more than one category.

Table 8 and Figure 2 display the number of final decisions issued.

TABLE 8 FINAL DECISIONS ISSUED FY2006- FY2010	
FY2006	345
FY2007	319
FY2008	354
FY2009	271
FY2010	269

Figure 2
FY 2010 FINAL DECISIONS ISSUED BY HEALTH SERVICE AREAS



Note: Figure does not include 2 out-state decisions.

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 2, 2010, the covered capital expenditure threshold was $2,942,500. The threshold is updated every January.

TABLE 9
FINAL DECISIONS ACTIVITY CATEGORY
FY2006 - FY2010

Approved	**FY2006**	**FY2007**	**FY2008**	**FY2009**	**FY2010**
Acquire, Begin, or Replace a Health Facility	57	51	71	49	44
Change in Bed Capacity	26	29	20	37	43
Covered Clinical Services	255	237	228	190	192
Covered Capital Expenditures	33	30	30	35	39
Disapproved					
Acquire, Begin, or Replace a Health Facility	2	2	2	1	5
Change in Bed Capacity	0	1	1	2	13
Covered Clinical Services	2	1	2	0	2
Covered Capital Expenditures	0	0	1	0	9

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
FY2006 - FY2010

	Approved	**Approved With Conditions**	**Disapproved**	**TOTALS**
Number of Final Decisions				
FY2006	234	106	3	345
FY2007	257	58	4	319
FY2008	291	59	4	354
FY2009	240	27	3	271
FY2010	225	29	15	269
Total Project Costs				
FY2006	$1,559,834,963	$837,565,409	$22,706,628	$2,397,465,372
FY2007	$1,577,574,167	$325,128,269	$ 1,765,604	$1,904,468,040
FY2008	$2,794,327,552	$719,560,182	$26,055,809	$3,539,943,543
FY2009	$ 791,637,143	$317,924,357	$ 931,675	$1,110,493,175
FY2010	$ 712,964,774	$ 82,921,512	$36,912,278	$ 832,798,564

Note: Final decisions include emergency CON applications.

CERTIFICATE OF NEED ACTIVITY SUMMARY COMPARISON

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

TABLE 11
CON ACTIVITY COMPARISON
FY2006 - FY2010

	Number of Applications	Difference from Previous Year	Total Project Costs	Difference from Previous Year
Letters of Intent Submitted				
FY2006	562	N/A	$3,156,853,978	N/A
FY2007	582	4%	$3,316,323,030	5%
FY2008	521	(10%)	$3,032,871,348	(9%)
FY2009	335	(36%)	$851,958,151	(72%)
FY2010	435	30%	$1,675,525,170	97%
Applications Submitted				
FY2006	383	N/A	$2,696,930,804	N/A
FY2007	320	(16%)	$3,097,185,206	15%
FY2008	388	21%	$2,577,833,078	(17%)
FY2009	219	(44%)	$604,642,399	(77%)
FY2010	303	38%	$1,503,768,132	149%
Final Decisions Issued				
FY2006	345	N/A	$2,397,456,372	N/A
FY2007	319	(8%)	$1,904,468,040	(21%)
FY2008	354	11%	$3,539,943,543	86%
FY2009	271	(23%)	$1,110,493,175	(69%)
FY2010	269	(1%)	$ 832,798,564	(25%)

Note: Final decisions Issued include Emergency CONs and swing bed applications.

AMENDMENTS

The Rules allow an applicant to request to amend an approved CON for projects that are not complete. The Department has the authority to decide when an amendment is appropriate or when the proposed change is significant enough to require a separate application. Typical reasons for requesting amendments include:

- **Cost overruns.** The Rules allow the actual cost of a project to exceed the approved amount by 15 percent of the first $1 million and 10 percent of all costs over $1 million. Fluctuations in construction costs can cause projects to exceed approved amounts.

- **Changes in the scope of a project.** An example is the addition of construction or renovation required by regulatory agencies to correct existing code violations that an applicant did not anticipate in planning the project.

- **Changes in financing.** Applicants may decide to pursue a financing alternative better than the financing that was approved in the CON.

Rule 9413 permits that the review period for a request to amend a CON-approved project be no longer than the original review period.

TABLE 12 provides a summary of amendment requests received by the Department and the time required to process and issue a decision.

TABLE 12
AMENDMENTS RECEIVED AND DECISIONS ISSUED
FY2006 - FY2010

	FY2006	FY2007	FY2008	FY2009	FY2010
Amendments Received	77	61	68	90	85
Amendment Decisions Issued	97	61	71	91	87
Percent Issued within Required Time Frame	87%	98%	71%	93%	98%

NEW CAPACITY

Table 13 provides a comparison of existing covered services, equipment and facilities already operational to new capacity approved in FY 2010. One hundred and twenty-seven (127) of the 254 approvals in FY 2010 were for new or additional capacity. The remaining approvals were for replacement equipment, renovations and other capital expenditures.

TABLE 13
COVERED CLINICAL SERVICES AND BEDS
FY2010

Covered Clinical Services/Beds	Existing Sites	Existing Units/Beds	New Sites	New Units/Beds
Air Ambulances	10	13	1	1
Cardiac Catheterization Services	64	191	1	9
Open Heart Surgical Services	34	N/A	0	N/A
Surgical Services	246	1,343	3	17
CT Scanners Services	290	381	19	24
MRI Services	251	208	9	11
PET Services	70	26	6	0
Lithotripsy Services	71	11	5	0
MRT Services	65	117	0	7
Transplant Services	5	N/A	2	N/A
Hospitals	174	26,238	0	33
NICU Services	22	621	0	0
Short-term Nursing (Swing Beds)	31	294	2	15
Nursing Homes/HLTCU	439	47,293	23	1,167
Psychiatric Hospitals/Units	62	2,242	0	3

Note: Table 13 does not account for facilities closed, services or equipment no longer operational, or beds delicensed and returned to the various bed pools.

COMPLIANCE ACTIONS

There were 326 projects requiring follow-up for FY 2010 based on the Department's Monthly Follow-up/Monitoring Report as shown in **Table 14.**

TABLE 14 FOLLOW UP AND COMPLIANCE ACTIONS FY2006 - FY2010					
	FY2006	**FY2007**	**FY2008**	**FY2009**	**FY2010**
Projects Requiring Follow-up	310	413	417	379	326
Approved CONs Expired	N/A	24	88	155	217
Compliance Orders Issued	0	2	1	4	0

Note: CONs are expired due to non-compliance with terms and conditions of approval or recipient has notified the Department that the approved-project was not implemented or the site is no longer providing the covered service/beds.

ANALYSIS OF CERTIFICATE OF NEED PROGRAM FEES AND COSTS

Section 20161(3) sets forth the fees to be collected for CON applications. The fees are based on total project costs and are set forth in **Figure 3**.

FIGURE 3 CON APPLICATION FEES	
Total Project Costs	**CON Application Fee**
$0 to 500,000	$1,500
$500,001 to 4,000,000	$5,500
$4,000,001 and above	$8,500

Table 15 analyzes the number of applications by fee assessed.

TABLE 15 NUMBER OF CON APPLICATIONS BY FEE FY2006 - FY2010					
CON Fee	**FY2006**	**FY2007**	**FY2008**	**FY2009**	**FY2010**
$ 0*	4	6	4	1	6
$1,500	84	75	128	103	113
$5,500	191	141	151	76	107
$8,500	104	98	109	39	77
TOTALS	383	320	392	219	303

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

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

TABLE 16 CON PROGRAM COST AND REVENUE SOURCES FOR FY2006 – FY2010					
	FY2006	**FY2007**	**FY2008**	**FY2009**	**FY2010**
Program Cost	$1,877,100	$1,741,300	$1,960,655	$1,871,395	$1,972,254
Fees/Funding	$1,884,849	$1,688,000	$1,743,926	$1,095,048	$1,423,451
Fees % of Costs	100%	97%	89%	59%	%72

Source: MDCH Budget and Finance Administration.

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY 2010, the CON Commission revised the review standards for Air Ambulance Services, Bone Marrow Transplantation (BMT) Services, Heart/Lung and Liver (HLL) Transplantation Services, Magnetic Resonance Imaging (MRI) Services, Neonatal Intensive Care Services/Beds (NICU), Pancreas Transplantation Services, and Psychiatric Beds and Services.

The revisions to the CON Review Standards for Air Ambulance Services received final approval by the CON Commission on June 10, 2010 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 August 12, 2010. The final language changes include the following:

- Updated the definition of “air ambulance service.”
- Redefined “base of operations.”
- Added a definition for “existing air ambulance.”
- Expanded the definition of patient transport to include advance life support intercepts.
- Added a new definition for organ transport and allowance for an organ transport to count for volume purposes for an air ambulance with two (2) air ambulances or at the time of application for expansion to a second unit.
- Modified the expansion language to utilize only historical volume.
- Modified the replacement language for an air ambulance to mirror the expansion language within the standards.
- Updated the methodology for projecting patient transports.
- Updated the project delivery requirements.
- Other technical changes.

The revisions to the CON Review Standards for BMT Services received final approval by the CON Commission on March 25, 2010 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 28, 2010. The final language changes include the following:

- Under Section 1, modified the language consistent with recent changes in other CON review standards.
- Definition for "licensed site" clarified based on current Department practice.
- Under Section 2(1)(t), redefined planning area to add a second adult planning area.
- Under Section 2(1)(w), added a definition for Tumor Registry as referenced in Section 8.
- "Implementation plan" moved to Section 3(4).
- Under Section 3(5), identified a cap of three in planning area one and a cap of one in planning area two.
- Under Section 3(6), the volume projection for adult BMT services is increased from 10 to 30 of which at least 10 are allogeneic transplant procedures. The volume projection for pediatric BMT services remains at 10 but at least 5 must be allogeneic transplant procedures.
- Under Section 3(10), added language to clarify that the written consulting agreement must be with an existing in-state or out-of-state Foundation for the Accreditation of Cellular Therapy (fact) accredited transplant unit that performs both allogeneic and autologous transplants for either adult and/or pediatrics.
- Under Section 3(10)(a)(iv)(A) and (B), reduced the number of site visits to three.
- Under sections 3(10)(b)(i), 7(1)(c)(i)(D) and (E), 7(1)(c)(iv)(A) and (B), 7(1)(c)(vi)(D), 7(1)(d)(v), modified language based on the recommendation that autologous only programs would no longer be allowed.
- Acquisition language (previous Section 8) moved to Section 4. For administrative feasibility,

changed “the CON granted pursuant to this Section shall automatically expire” to “the Department may expire the CON granted pursuant to this Section.”

- Under Section 5(3)(a), modified to award points based on the straight-line distance to the nearest existing bmt program of the type applied for (adult or pediatric) instead of being based on the number of BMT services within the health service area (HSA).
- Clarified Section 5(3)(b)(ii) based on administrative practice.
- Under Section 5(3)(d), added language to award points based on the number of necessary support services/personnel as identified in Section 6 (project delivery requirements) that the applicant has available on-site on the date the application is submitted to the Department.
- Based on current administrative practice, modified the language in Section 5(4) consistent with recent changes in other CON review standards.
- Split Section 7(1)(c)(iv)(C) into two subsections: 7(1)(c)(iv)(C) and (D).
- Under Section 7(1)(d)(i)(A) and (B), the volume maintenance for adult BMT services is increased from 10 to 30 of which at least 10 are allogeneic transplant procedures. The volume projection for pediatric BMT services remains at 10 but at least 5 must be allogeneic transplant procedures.
- Under Section 8, added language to identify the source of data for documentation of projections.
- Other technical changes.

The revisions to the CON Review Standards for HLL Transplantation Services received final approval by the CON Commission on March 25, 2010 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 28, 2010. The final language changes include the following:

- Under Section 1, modified the language consistent with recent changes in other CON review standards.
- "Implementation plan" moved to Section 3(2).
- Definition for "licensed site" clarified based on current Department practice.
- Removed definition for “transplant and health policy center” as it is no longer referenced in the standards.
- Removed definition for “transplant support program” as it is not referenced in the standards.
- Under Section 3(5), added liver transplantation services to the joint sharing arrangement language.
- Under Section 5(1) and (2), added language relevant to the joint sharing arrangement and consistent with Section 4(1) and (2).
- Based on current administrative practice, modified the language in Section 6(4) consistent with recent changes in other CON review standards.
- Added language under Section 7(1)(c)(ii) to clarify the requirements to comply with the Organ Procurement and Transplantation Network (OPTN). Removed sections 8, 9, and 10 as they are no longer needed given the clarification to Section 7(1)(c)(ii).
- Updated the language under Section 7(1)(c)(ix) as required by the federal OPTN.
- Other technical changes.

The revisions to the CON Review Standards for MRI Services received final approval by the CON Commission on September 10, 2009 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 5, 2009. The final language changes include the following:

- Streamlined Section 1.
- Technical edits in Section 2.
- Added an exclusion in Section 2 (1)(dd) for MRI Simulators. The MRI simulator language is consistent with the requirements in the CON Review Standards for Computed Tomography (CT) Scanner Services. The use of an MRI simulator would not need an approval for an MRI CON if used only for Megavoltage Radiation Therapy (MRT) treatment planning purposes. In the event that the facility wants to use the MRI for billable diagnostic procedures, then the facility would need an approved MRI CON.
- Streamlined and reorganized Sections 3 - 7.
- Added an exception to the criteria for conversion of a mobile to a fixed MRI in Section 3(2)(b)(iii) to allow for a hospital with 3,000 MRI adjusted procedures, 24-hour emergency care services, and at least 20,000 emergency room visits within a 12-month period to convert from a mobile to a fixed. Further, a maintenance volume of 3,000 actual MRI adjusted procedures per unit was added to the project delivery requirements, Section 12(1)(d)(i).
- Modified Section 3(2)(d) to clarify that an applicant applying under Section 3(2)(b)(iii) shall locate the fixed MRI unit at the same site as the existing host site.
- Eliminated the draft contract requirement within expansion and replacement for mobile services.
- Modified the expansion criteria for mobile services to utilize only historical utilization (adjusted procedures), not physician commitments (available adjusted procedures).
- Eliminated the exception for relocating outside of the relocation zone, but within the planning area, as this exception is obsolete and not utilized.
- Modified the project delivery requirements.
- Other technical edits including those based on administrative practice.

The revisions to the CON Review Standards for NICU received final approval by the CON Commission on June 10, 2010 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 August 12, 2010. The final language changes include the following:

- Under Section 1, modified the language consistent with recent changes in other CON review standards.
- Under subsections 9(1) and (3), modified the language consistent with recent changes in other CON review standards.
- Other technical changes.

The revisions to the CON Review Standards for Pancreas Transplantation Services received final approval by the CON Commission on September 10, 2009 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 5, 2009. The final language changes include the following:

- Streamlined Section 1.
- Definitions for "initiate or implement" and "licensed site" clarified based on current Department practice.
- "Implementation plan" moved to Section 3(2).
- The projected and maintenance volume for pancreas transplantation procedures is changed from 12 to 2. These changes occur in sections 3(3) and 4(1)(i). This conforms to the OPTN requirement of 1 every 6 months.

- Tied to item 4, a maintenance requirement of 80 kidney transplants and/or pancreas transplantation procedures to be performed biennially (every two years). This change can be found in Section 4(1)(c)(ii).
- Other technical changes.

The revisions to the CON Review Standards for Psychiatric Beds and Services received final approval by the CON Commission on September 10, 2009 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 5, 2009. The final language changes include the following:

- Section 1 streamlined.
- Based on current administrative practice, the high occupancy language of Section 7(3) was revised to clarify that the planning area must be at a bed need of zero or over-bedded to use the provision.
- Based on current administrative practice, modified the language in Section 10(4).
- Added criteria under Section 11(2) that requires outstanding debt obligations owed to the state of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP) have been paid in full.
- Added quality criteria under Section 11(3) that requires the health facility for the proposed project has not been cited for a state or federal code deficiency within the 12 months prior to the submission of the application including requirements if there have been code deficiencies.
- Updated the bed need numbers with a base year of 2008 and the planning year of 2015, the ratio per 10,000 adult population, and the use rate per 1000 population age 0-17 (Appendices A – D). The effective date for the bed need methodology numbers is the same as the effective date of the Standards.)
- Other technical changes.

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