MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) PROGRAM

ANNUAL ACTIVITY REPORT

October 2021 through September 2022
(FY2022)

Michigan Department of Health & Human Services

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EXECUTIVE SUMMARY

One of the Michigan Department of Health and Human Services (MDHHS 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 34th report to the Commission and covers the period beginning October 1, 2021, through September 30, 2022 (FY 2022). 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 Policy, Planning and Operational Support Administration provides support for the CON Commission (Commission) and its Standard Advisory Committees (SACs). The Commission is responsible for setting review standards and designating the list of covered services. The Commission may utilize a SAC to assist in the development of proposed CON review standards, which consists of a 2/3 majority of experts in the subject area. Further, the Commission, if determined necessary, may submit a request to the Department to engage the services of consultants or request the Department to contract with an organization for professional and technical assistance and advice or other services to assist the Commission in carrying out its duties and functions.

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

During FY 2022, the Department has continued to make process improvements in both the Policy and Evaluation Sections.

The Evaluation Section continued to utilize the streamlined, electronic process for filing Emergency CON applications to assist health care providers statewide in planning and implementing bed surge plans to adequately treat patients impacted by COVID-19, RSV, etc., in Michigan, and tirelessly worked to other Governmental agencies and health care organizations to make the processes successful. The Department promptly developed new processes, data tracking systems and forms to administer the newly revised CON Standards for Cardiac Catheterization Services. The Department completed statewide compliance review of all facilities providing Cardiac Catheterization and Megavoltage Radiation Therapy Services. The Section also facilitated webinars to provide up-to-date information on revised CON standards, application processes and CON annual survey reporting requirements.

The Policy Section assisted the Commission to make the necessary modifications to the CON Review standards to better reflect practice, improve quality, and add clarity to the standards; revised the definition of Hospital Bed to exclude unlicensed beds in Hospital Bed Review Standards; added an exception for areas meeting the bed need, restricted the movement of beds approved under the exception, modified requirements to initiate child/adolescent beds, and added comparative review criteria for bariatric rooms in Psychiatric Beds and Services; modified and added definitions, updated requirements to initiate a fixed Magnetic Resonance Imaging (MRI) Scanner Service in MRI Review Standards; modified requirements to replace a Megavoltage Radiation Therapy (MRT) service to a new site in rural counties, added language to provide equal additive factors for CT-guided MRT in MRT Review Standards; revised methodology for computing Positron Emission Tomography (PET) data units and revised the initiation volume requirements for mobile and fixed sites in PET Review Standards; added language to Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services language to clarify staffing requirements; a workgroup is reviewing changes for Computed Tomography (CT) Scanner Services Review Standards; and a workgroup is reviewing changes for Nursing Home and Hospital Long-Term-Care Unit Beds Review Standards. (Note: With the exception of Hospital Beds, these changes will become effective in FY2023.)

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

CON Required

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

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

CON Application Process

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

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

There are three types of CON review: nonsubstantive, substantive individual, and comparative. The Administrative Rules for the CON program establish timelines 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 2022 in Review

In FY 2022, there were 292 Letters of Intent received resulting in 228 applications filed for CON review and approval. In addition, the Department received 74 amendments to previously approved applications. In total, the Department approved 254 proposed projects resulting in approximately $1,642,388,032 of new capital expenditures into Michigan's healthcare system. The Department also surveyed 1,091 facilities and collected statistical data. As required by Administrative Rules, the Department was timely in processing Letters of Intent, pending CON applications and issuing its decisions on pending applications. These measures, along with the other information contained in this report, aid the Commission in its duties as set forth in Part 222 of the Public Health Code.

During FY2022, the CON Commission revised the review standards for Hospital Beds, Magnetic Resonance Imaging (MRI), Megavoltage Radiation Therapy (MRT), Psychiatric Beds and Services, Neonatal Intensive Care Services/Beds (NICU), Positron Emission Tomography (PET), Computed Tomography (CT) Scanner Services, and Nursing Home and Hospital Long-Term-Care Unit Beds (NH-HLTCU).

This report is filed by the Department in accordance with MCL 333.22221(f). The report presents information about the nature of these CON applications and decisions, as well as the Commission's actions during the reporting period. Several tables include benchmarks for timely processing of applications and issuing decisions as set forth in the CON Administrative Rules. Note that the data in the report represents some applications that were carried over from last fiscal year while others may be carried over into next fiscal year.

HISTORICAL OVERVIEW OF MICHIGAN'S CERTIFICATE OF NEED PROGRAM

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

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

1988 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 standards now allow applicants to reasonably assess requirements for approval, before filing an application. 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 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 healthcare 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 FY2020.

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 A Standards Advisory Committee (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 healthcare providers or professionals, purchasers, consumers, and payers.

MDHHS The Michigan Department of Health and Human Services 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 Policy and Legislative Administration.

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

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

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

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

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

LETTERS OF INTENT

The CON Administrative Rules, specifically Rule 9201, provides that Letters of Intent (LOI) must be processed within 15 days of receipt. Processing an LOI includes entering data in the management information system, verifying historical facility information, and obtaining proof of authorization to do business in Michigan. This information determines the type of review for the proposed project, and the Department then notifies the applicant of applicable application forms to be completed.

Table 1 provides an overview of the number of LOIs received and processed in accordance with the above-referenced Rule.

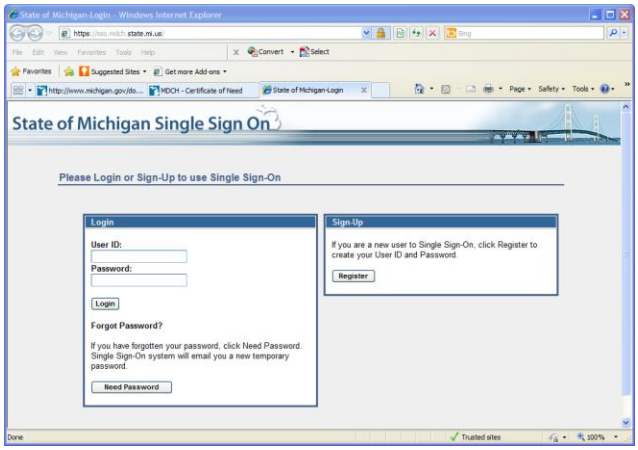
TABLE 1
LETTERS OF INTENT RECEIVED AND PROCESSED WITHIN 15 DAYS
FY2018 - FY2022

	LOIs Received	Processed within 15 Days	Percent Processed within 15 Days	Waivers Processed*
FY2018	371	370	99%	73
FY2019	365	363	99%	79
FY2020	420	418	99%	42
FY2021	396	394	99%	37
FY2022	292	288	99%	53

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

In FY 2022, LOIs were processed in a timely manner as required by Administrative Rule and available for public viewing on the online application system. The online system allows for faster processing of LOIs and subsequent applications by the Evaluation Section, as well as modifying these applications by applicants when needed.

In 2006, Michigan became the first state to have an online application and information system. Today 100% of all LOIs and applicable applications are submitted online.



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TYPES OF CERTIFICATE OF NEED APPLICATION REVIEWS

The Administrative Rules also establish three types of project reviews: nonsubstantive, substantive individual, and comparative. The Rules specify the time frames by which the Bureau (Evaluation Section) 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 types of projects that are potentially eligible for nonsubstantive review:

- Acquire an existing health facility
- Replace a health facility within the replacement zone and below the covered capital expenditure
- Add a host site to an existing mobile network/route that does not require data commitments
- Replace or upgrade a covered clinical equipment
- Acquire or relocate an existing freestanding covered clinical service

The Rules allow the Bureau (Evaluation Section) 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 (Evaluation Section) 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 (Evaluation Section) 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 FY2022*	
Neonatal Intensive Care Unit	Nursing Home/HLTCU Beds
Hospital Beds	Nursing Home Beds for Special Population Groups
Psychiatric Beds	Psychiatric Beds for Special Population Groups
Transplantations	

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
FY2018 - FY2022

	FY2018	FY2019	FY2020	FY2021	FY2022
Nonsubstantive*	154	132	118	191	146
Substantive Individual	142	72	80	84	78
Comparative	0	6	36	8	4
TOTALS	296	210	234	283	228

∗ Includes 7 swing bed applications; does not include Emergency CONs.

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 FY2018 - FY2022*					
	FY2018	**FY2019**	**FY2020**	**FY2021**	**FY2022**
Applications Received	296	210	234	283	228
Processed within 15 Days	295	210	234	282	227
Percent Processed within 15 Days	99%	100%	100%	99%	99%

Note: Includes swing bed applications; does not include Emergency CONs.

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 FY2018- FY2022*					
	FY2018	**FY2019**	**FY2020**	**FY2021**	**FY2022**
Nonsubstantive	36	37	42	37	40
Substantive Individual	102	114	98	105	118
Comparative	N/A	94	112	227	113

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

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 (Evaluation Section) attempts to issue emergency CON decisions to the Director for final review and approval within 10 days from receipt of request. In FY2022 the Bureau issued the 14 emergency CON decisions within an average of three (3) days.

TABLE 5 *EMERGENCY CON DECISIONS ISSUED FY2018 - FY2022*					
	FY2018	**FY2019**	**FY2020**	**FY2021**	**FY2022**
Emergency CONs Issued	0	0	105	26	14
Percent Issued within 10 Working Days	N/A	N/A	100%	100%	100%

PROPOSED DECISIONS

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

Table 6 shows the number of proposed decisions by type, issued within the applicable timeframes set forth in the Administrative Rules 325.9206 and 325.9207: 45 days for nonsubstantive, 120 days for substantive individual, and 150 days for comparative reviews, or any requested extension(s) to the review cycle.

TABLE 6 PROPOSED DECISIONS ISSUED FY2018- FY2022						
	Nonsubstantive		**Substantive Individual**		**Comparative**	
	Issued	Issued on Time	Issued	Issued on Time	Issued	Issued on Time
FY2018	174	100%	107	100%	0	N/A
FY2019	123	100%	98	100%	4	100%
FY2020	119	100%	83	100%	34	100%
FY2021	173	100%	58	100%	34	100%
FY2022	149	100%	93	100%	4	100%

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

TABLE 7 COMPARISON OF PROPOSED DECISIONS BY DECISION TYPE FY2018- FY2022					
	Approved	**Approved w/ Conditions**	**Disapproved**	**Percent Disapproved**	**TOTAL**
FY2018	214	65	2	0.7%	281
FY2019	162	62	2	0.8%	226
FY2020	156	64	16	7%	236
FY2021	150	92	29	9%	271
FY2022	150	92	3	1.2%	245

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 FY2018- FY2022*	
FY2018	276
FY2019	224
FY2020	314
FY2021	287
FY2022	261

FIGURE 2
FY 2022 FINAL DECISIONS ISSUED BY HEALTH SERVICE AREAS

Note: Figure 2 does not include 4 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 imaging services, computed tomography scanner services, and air ambulance services.

Covered Capital Expenditures
This category includes capital expenditure projects in the 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. In 2021, the covered capital expenditure threshold was $3,425,000 and as of January 1, 2022, the covered capital expenditure threshold was increased to $3,492,500. The threshold is updated in January of every year.

TABLE 9 *FINAL DECISIONS ACTIVITY CATEGORY FY2018 - FY2022*					
Approved	**FY2018**	**FY2019**	**FY2020**	**FY2021**	**FY2022**
Acquire, Begin, or Replace a Health Facility	56	27	36	43	50
Change in Bed Capacity	40	40	136	54	48
Covered Clinical Services	180	164	160	163	237
Covered Capital Expenditures	32	36	58	53	66
Disapproved					
Acquire, Begin, or Replace a Health Facility	1	2	2	23	1
Change in Bed Capacity	0	0	2	28	2
Covered Clinical Services	0	0	0	1	0
Covered Capital Expenditures	0	0	1	25	2

Note: Totals above may not match Final Decision totals because one application 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 FY2018 - FY2022*				
	Approved	**Approved with Conditions**	**Disapproved**	**Totals**
Number of Final Decisions				
FY2018	210	65	1	276
FY2019	162	62	2	226
FY2020	147	167	2	316
FY2021	168	90	29	287
FY2022	191	68	2	261
Total Project Costs				
FY2018	$1,590,933,280	$544,275,880	$200,000,000	$2,335,209,160
FY2019	$828,424,031	$494,288,355	$174,010,658	$1,496,723,044
FY2020	$2,023,996,054	$292,720,764	$22,323,062	$2,339,039,880
FY2021	$1,092,194,095	$288,134,537	$562,706,545	$1,943,035,177
FY2022	$1,220,532,622	$421,855,410	$43,388,140	$1,685,776,172

Note: Final decisions include emergency CON applications.

In FY2022, 2 CON applications received final decision of disapproval from the Department. One (1) project was to begin operation of a new nursing home with 50 beds in Planning Area-47 (Livingston County). One (1) project was to add 60 adult psychiatric beds to an existing psychiatric hospital in Health Service Area-4.

CERTIFICATE OF NEED ACTIVITY SUMMARY COMPARISON

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

TABLE 11 *CON ACTIVITY COMPARISON FY2018 - FY2022*				
	Number of Applications	**Difference from Previous Year**	**Total Project Costs**	**Difference from Previous Year**
Letters of Intent Processed				
FY2018	397	16%	$2,660,753,511	43%
FY2019	365	(8%)	$2,876,054,374	(8%)
FY2020	420	15%	$1,861,451,187	(35%)
FY2021	396	(6%)	$2,443,097,718	31%
FY2022	300	(24%)	$1,845,302,652	(24%)
Applications Submitted				
FY2018	296	8%	$2,575,451,177	61%
FY2019	212	(28%)	$1,237,316,450	(52%)
FY2020	339	61%	$2,507,922,695	3%
FY2021	309	(9%)	$1,703,931,501	(32%)
FY2022	255	(17%)	$2,321,037,942	36%
Final Decisions Issued				
FY2018	276	2%	$2,335,209,160	70%
FY2019	225	(18%)	$1,333,240,369	(43%)
FY2020	316	40%	$2,339,039,880	75%
FY2021	288	(9%)	$1,944,965,809	(17%)
FY2022	261	(9%)	$2,517,447,509	29%

Note: Applications submitted, and 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 or a change in covered clinical equipment.

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

- **Change in construction start date** – The Rules allow an Applicant to request an extension to start construction/renovation for an approved project.

Table 12 provides a summary of amendment requests received by the Department and the time required to process and issue a decision. 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 *AMENDMENTS RECEIVED AND DECISIONS ISSUED FY2018 - FY2022*					
	FY2018	**FY2019**	**FY2020**	**FY2021**	**FY2022**
Amendments Received	80	92	57	57	74
Amendment Decisions Issued	75	90	66	57	61
Percent Issued within Required Time Frame	100%	100%	100%	100%	100%

NEW CERTIFICATE OF NEED CAPACITY

Table 13 provides a comparison of existing covered services, equipment and facilities already operational to new capacity approved in FY 2022. Eighty-one (81) of the 251 CON approvals in FY 2022 were for new or additional capacity. The remaining approvals were for replacement equipment, relocation of existing services, acquisitions, renovations and other capital expenditures.

TABLE 13 *COVERED CLINICAL SERVICES AND BEDS FY2022*				
Covered Clinical Services/Beds	**Existing Sites**	**Existing Units/Beds**	**New Sites**	**New Units/Beds**
Air Ambulances	15	18	0	0
Cardiac Catheterization Services	61	250	3	7
Primary PCI	0	N/A	1	N/A
Elective PCI	15	N/A	3	N/A
Open Heart Surgical Services	35	1	0	0
Surgical Services	288	1502	11	31
CT Scanners Services	277	426	4	10
MRI Services	314	325	4	3
PET Services	108	30	6	3
Lithotripsy Services	101	11	3	0
MRT Services	71	127	1	3
Transplant Services	6	N/A	N/A	N/A
Hospitals	185	26,267	0	0
NICU Services	21	653	0	0
SCN Services	17	104	2	9
Extended Care Services Program (Swing Beds)	38	352	6	55
Nursing Homes/HLTCU	482	49,346	3	201
Psychiatric Hospitals/Units	77	3,470	9	398
Psychiatric Flex Beds	4	46	0	0

Note: The source for the existing site and unit/bed information for Table 13 was the 2021 CON Annual Survey, and CON applications approved but not yet operational. Table 13 does not account for projects expired, facilities closed, and beds delicensed and returned to the various bed pools since the last survey period for CY 2021. New sites include mobile host sites for CT, Lithotripsy, MRI and PET services.

COMPLIANCE ACTIONS

Table 14 shows there were 261 projects requiring follow-up for FY 2022 based on the Department's Monthly Follow-up/Monitoring Report as shown below.

TABLE 14 *FOLLOW UP AND COMPLIANCE ACTIONS FY2018 - FY2022*					
	FY2018	**FY2019**	**FY2020**	**FY2021**	**FY2022**
Projects Requiring 1-yr Follow-up	272	226	225	314	261
Approved CONs Expired	118	83	87	95	62
Compliance Orders Issued	48	30	65	95	26

Note: CONs are expired due to non-compliance with terms and conditions of approval or when the recipient has notified the Department that either the approved-project was not implemented or the site is no longer providing the covered service/beds. Compliance Orders include orders issued by the Department under MCL 333.22247, settlement agreements offered or remedies for non-compliance. The Department completed statewide compliance review of all facilities providing Cardiac Catheterization and Megavoltage Radiation Therapy Services. Other compliance orders included individual facility's compliance issues related to MRI Services.

ANALYSIS OF CERTIFICATE OF NEED PROGRAM FEES AND COSTS

Section 20161(3) sets forth the fees to be collected for CON applications. Figure 3 shows the application fees based on total projects costs and additional fees per the new fee structure, effective October 15, 2013, approved under House Bill No. 4787.

FIGURE 3 *CURRENT CON APPLICATION FEES*	
Total Project Costs	**CON Application Fee**
$0 to $500,000	$3,000
$500,001 to $3,999,999	$8,000
$4,000,000 to $9,999,999	$11,000
$10,000,000 and above	$15,000
Additional Fee Category	**Additional Fee**
Complex Projects (i.e. Comparative Review, Acquisition or replacement of a licensed health facility with two or more covered clinical services.)	$3,000
Expedited Review - Applicant Request	$1,000
Letter of Intent (LOI) Resulting in a Waiver	$500
Amendment Request to Approved CON	$500
CON Annual Survey	$100 per Covered Clinical Service

Table 15A analyzes the number of applications by fee assessed.

TABLE 15A *NUMBER OF CON APPLICATIONS BY FEE FY2018 – FY2022*					
CON Fee	**FY2018**	**FY2019**	**FY2020**	**FY2021**	**FY2022**
*$ 0**	1	0	106	32	21
$3,000	123	76	78	84	77
$8,000	86	87	79	101	64
$11,000	30	23	25	58	36
$15,000	54	25	53	34	57
TOTAL	292	211	341	309	255

Note: Table 15A may not match fee totals in Table 16, as Table 16 accounts for refunds, overpayments, MFA funding, etc.

** No fees are required for emergency CON and swing beds applications.*

Table 15B analyzes the fees collected for the additional fee categories. More than one fee category may be assessed for one application.

TABLE 15B *NUMBER OF ADDITIONAL CON APPLICATION FEES FY2018 – FY2022*					
CON Fee Category	**FY2018**	**FY2019**	**FY2020**	**FY2021**	**FY2022**
Complex Project	2	5	36	7	5
Expedited Review	52	29	41	26	12
*LOI Waiver**	77	79	45	37	53
*Amendment**	80	92	57	57	74
Annual Survey (Facilities)	1052	1066	1067	1094	1091

**Note: Some waivers and amendments do not require a fee based on the type of change requested.*

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

TABLE 16 *CON PROGRAM COST AND REVENUE SOURCES FOR FY2018– FY2022*					
	FY2018	**FY2019**	**FY2020***	**FY2021**	**FY2022**
Program Cost	$2,382,030	$2,114,316	$2,109,705	$2,463,147	$2,348,344
Fees/Funding	$2,607,045	$1,990,861	$2,447,531	$2,520,217	$2,204,660
Fees % of Costs	100%+	94%	100%+	100%+	94%

Source: MDHHS Budget and Finance Administration.

**Under Public Act 169 of 2020, for the fiscal year ending September 30, 2020 only, $3,000,000 of the money in the Certificate of Need program was transferred to and deposited into the general fund.*

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY2022, the CON Commission revised the review standards for Hospital Beds, Magnetic Resonance Imaging (MRI), Megavoltage Radiation Therapy (MRT), Psychiatric Beds and Services, Neonatal Intensive Care Services/Beds (NICU), Positron Emission Tomography (PET), Computed Tomography (CT) Scanner Services, and Nursing Home and Hospital Long-Term-Care Unit Beds (NH-HLTCU).

The revisions to the CON Review Standards for Hospital Beds received final approval by the CON Commission on December 9, 2021 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 28, 2022. The final language changes include the following:

- Section 2(1): Modified/added definitions as follows:
  - (q) "Hospital bed" means a bed within the licensed bed complement at a licensed site of a hospital licensed under Part 215 of the Code, excluding (i) hospital beds certified for long-term care as defined in Section 20106(6) of the Code, (ii) unlicensed newborn bassinets, AND (iii) UNLICENSED BEDS.
  - (tt) "VERIFIABLE DATA" MEANS DATA (INPATIENT PATIENT DAYS) FROM THE MOST RECENT ANNUAL SURVEY OR MORE RECENT DATA THAT CAN BE VALIDATED BY THE DEPARTMENT.
- Other technical edits.

The following review standards were reviewed with an anticipated completion in FY2023:

Magnetic Resonance Imaging (MRI): Proposed action was taken by the Commission at its June 16, 2022 meeting. The standards were submitted to the Joint Legislative Committee (JLC) and a Public Hearing was held. The Commission took final action at its September 15 meeting, and the standards will become effective in FY2023.

Megavoltage Radiation Therapy (MRT): Proposed action was taken by the Commission at its June 16, 2022 meeting. The standards were submitted to the JLC and a Public Hearing was held. The Commission took a final action at its September 15 meeting, and the standards will become effective in FY2023.

Psychiatric Beds and Services: Proposed action was taken by the Commission at its September 15, 2022 meeting. The standards were submitted to the JLC and a Public Hearing was held. The Commission is scheduled to take final action at its December 8, 2022 Commission meeting, and the standards will become effective in FY2023.

Neonatal Intensive Care Services/Beds (NICU): Proposed action was taken by the Commission at its September 15, 2022 meeting. The standards were submitted to the JLC and a Public Hearing was held. The Commission is scheduled to take final action at its December 8, 2022 Commission meeting, and the standards will become effective in FY2023.

Positron Emission Tomography (PET): Proposed action was taken by the Commission at its September 15, 2022 meeting. The standards were submitted to the JLC and a Public Hearing was held. The Commission is scheduled to take final action at its December 8, 2022 Commission meeting, and the standards will become effective in FY2023.

Computed Tomography (CT) Scanner Services is being reviewed by an informal workgroup.

Nursing Home and Hospital Long-Term-Care Unit Beds (NH-HLTCU) is being reviewed by an informal workgroup.

APPENDIX I - CERTIFICATE OF NEED COMMISSION

Amy McKenzie, MD, CON Commission Chairperson
James B. Falahee, Jr., JD, CON Commission Vice-Chairperson
Justin B. Dimick, MD
Amy Engelhardt-Kalbfleisch, DO
Eric Ferguson, MD
Debra Guido-Allen, RN
Donald Haney
Ashok Kondur, MD
Melanie Lalonde
Lorissa MacAllister, PhD
Renee Turner-Bailey

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