

A photograph of the Michigan State Capitol building, featuring its iconic copper dome and classical architecture, set against a clear blue sky.

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) PROGRAM

ANNUAL ACTIVITY REPORT

***October 2023 through September 2024
(FY2024)***



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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 36th report to the Commission and covers the period beginning October 1, 2023, through September 30, 2024 (FY 2024). 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 2024, the Department has continued to make process improvements in both the Policy and Evaluation Sections.

The Evaluation Section launched and enhanced the recorded instructional aids for the Annual Survey online system to assist healthcare providers in understanding the survey reporting requirements and completing the health facility surveys. The Department completed statewide compliance review of all facilities providing Lithotripsy, NICU beds and SCN 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 in making the necessary modifications to the CON Review standards to better reflect practices, improve quality, and add clarity to the standards.

- Regulation for Air Ambulance Services began in the Bureau of EMS Trauma and Preparedness Rule Set 325.22101 through 325.22218 and was deregulated from the CON Commission Review Standards in FY2024;
- Added abbreviations as well as expanded definitions for clarity, added language for lease renewal and prohibited the withdrawal of a CT physician commitment during the review process in Computed Tomography (CT) Scanner Services Review Standards that were in effect during FY2024;
- Modified definitions and added flexibility to the addendum for Special Population Groups to allow for the initiation of a Freestanding Medical Psychiatric Unit and Medical Psychiatric Units in acute care settings, added a new pilot program for the initiation of child/adolescent psychiatric beds in Psychiatric Beds and Services Review Standards that were in effect during FY2024;
- Added language around replacement and relocation, updated method of collection and reviewing citation data, modified sections into subsections, and other technical edits to the Nursing Home and Hospital Long Term Care Unit (NH-HLTCU) Beds Review Standards that were in effect during FY2024;
- Modified reporting requirements for the STS Composite Star Rating System for related

- procedures in Open Heart Surgery Review Standards that were in effect during FY2024;
- Modified definitions, added language allowing continued operation for LTAC hospitals after closure, and other technical edits in the Hospital Beds Review Standards that were in effect during FY2024;
- In 2023 added language related to initiation of new MRT services in HSA 8, modified equivalent treatment visits and associated definitions in a table within the Megavoltage Radiation Therapy (MRT) Services/Units Review Standards that were in effect during FY2024;
- In 2024 modified definitions, updated the minimum volume requirements, added requirements to initiate, replace, and expand a surgical service, added requirements for Medicaid participation, updated terms of approvals for applicants in the project delivery requirements and documentation or projects section, and other technical edits for the Surgical Services Review Standards;
- In 2024 definitions were modified and project delivery requirements were updated to accommodate the rural emergency hospital designation in the Hospital Beds Review Standards;
- In 2024 technical edits were made to the Bone Marrow Transplantation (BMT) Services Review Standards; Surgical Services, Hospital Beds, and BMT Review Standards will be effective in FY2025;
- A Standard Advisory Committee (SAC) began in FY2024 to review the Cardiac Catheterization Review Standards and will be completed in FY2025;
- A workgroup began in FY2024 to review the Magnetic Resonance Imaging (MRI) Scanner Services Review Standards and will be completed in FY2025;
- A SAC will begin in FY2025 to review the Heart, Lung, and Liver (HLL) Transplantation Services Review Standards;
- A workgroup will begin in FY2025 to review the Psychiatric Beds and Services Review Standards; A workgroup will begin in FY2025 to review the County Designation requirements within 11 of the 14 Review Standards.

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 2024 in Review

In FY 2024, there were 255 Letters of Intent received resulting in 189 applications filed for CON review and approval. In addition, the Department received 66 amendments to previously approved applications. In total, the Department approved 195 proposed projects resulting in approximately \$2,773,710,342 of new capital expenditures into Michigan's healthcare system. The Department also surveyed 1,099 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 FY2024, the CON Commission deregulated the Air Ambulance review standards as well as revised the review standards for Computed Tomography (CT) Scanner Services, Psychiatric Beds and Services, Nursing Home and Hospital Long-Term-Care Unit (NH-HLTCU) Beds, Open Heart Surgery (OHS) Services, Hospital Beds, and Megavoltage Radiation Therapy (MRT).

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

<i>Commission</i>	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.
<i>NEWTAC</i>	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.
<i>SAC</i>	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.
<i>MDHHS</i>	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.
<i>Policy Section</i>	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.
<i>Evaluation Section</i>	<p>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.</p> <p>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.</p> <p>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.</p>

CERTIFICATE OF NEED PROCESS

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

<i>Letter of Intent</i>	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.
<i>Application</i>	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.
<i>Review Types and Time Frames</i>	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.
<i>Review Process</i>	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.
<i>Proposed Decision</i>	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.
<i>Final Decision</i>	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.

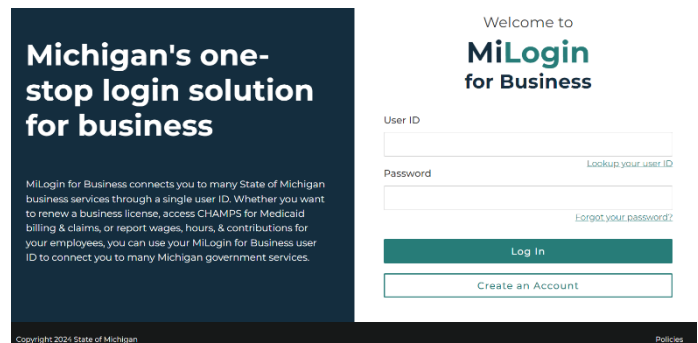
Table 1 provides an overview of the number of LOIs received and processed in accordance with the above-referenced Rule.

TABLE 1 LETTERS OF INTENT RECEIVED AND PROCESSED WITHIN 15 DAYS FY2020 - FY2024				
	LOIs Received	Processed within 15 Days	Percent Processed within 15 Days	Waivers Processed*
FY2020	420	418	99%	42
FY2021	396	394	99%	37
FY2022	292	288	99%	53
FY2023	301	301	100%	65
FY2024	255	255	100%	49

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

In FY 2024, 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.

<u>FIGURE 1</u> <i>Services/Beds Subject to Comparative Review in FY2024</i>	
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.

<u>TABLE 2</u> <i>APPLICATIONS RECEIVED BY REVIEW TYPE FY2020 - FY2024</i>					
	FY2020	FY2021	FY2022	FY2023	FY2024
<i>Nonsubstantive*</i>	118	191	146	113	120
<i>Substantive Individual</i>	80	84	78	79	65
<i>Comparative</i>	36	8	4	3	4
<i>TOTALS</i>	234	283	228	195	189

** Includes 0 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 FY2020 - FY2024					
	FY2020	FY2021	FY2022	FY2023	FY2024
Applications Received	234	283	228	195	193
Processed within 15 Days	234	282	227	195	192
Percent Processed within 15 Days	100%	99%	99%	100%	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 FY2020- FY2024					
	FY2020	FY2021	FY2022	FY2023	FY2024
Nonsubstantive	42	37	40	36	34
Substantive Individual	98	105	118	110	98
Comparative	112	227	113	148	92

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 FY2024 the Bureau issued the four (4) emergency CON decisions within an average of four (4) days.

TABLE 5 EMERGENCY CON DECISIONS ISSUED FY2020 - FY2024					
	FY2020	FY2021	FY2022	FY2023	FY2024
Emergency CONs Issued	105	26	14	6*	4
Percent Issued within 10 Working Days	100%	100%	100%	100%	100%

**Emergency CON - 1 application was submitted but withdrawn before a decision was to be issued.*

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 FY2020- FY2024						
	Nonsubstantive		Substantive Individual		Comparative	
	Issued	Issued on Time	Issued	Issued on Time	Issued	Issued on Time
<i>FY2020</i>	119	100%	83	100%	34	100%
<i>FY2021</i>	173	100%	58	100%	34	100%
<i>FY2022</i>	149	100%	93	100%	4	100%
<i>FY2023</i>	116	100%	76	100%	3	100%
<i>FY2024</i>	113	100%	60	100%	4	100%

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

TABLE 7 COMPARISON OF PROPOSED DECISIONS BY DECISION TYPE FY2020- FY2024					
	Approved	Approved w/ Conditions	Disapproved	Percent Disapproved	TOTAL
<i>FY2020</i>	156	64	16	7%	236
<i>FY2021</i>	150	92	29	9%	271
<i>FY2022</i>	150	92	3	1.22%	245
<i>FY2023</i>	159	35	1	0.5%	195
<i>FY2024</i>	149	28	0	0%	181

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.

FIGURE 2
FY 2024 FINAL DECISIONS ISSUED
BY HEALTH SERVICE AREAS

TABLE 8 FINAL DECISIONS ISSUED FY2020- FY2024	
<i>FY2020</i>	314
<i>FY2021</i>	287
<i>FY2022</i>	261
<i>FY2023</i>	198
<i>FY2024</i>	190



Note: Figure 2 does not include 1 out-state decision.

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 2023, the covered capital expenditure threshold was \$3, 735,000 and as of January 1, 2024, the covered capital expenditure threshold was increased to \$4,002,500. The threshold is updated in January of every year.

TABLE 9
FINAL DECISIONS ACTIVITY CATEGORY
FY2020 - FY2024

Approved	FY2020	FY2021	FY2022	FY2023	FY2024
<i>Acquire, Begin, or Replace a Health Facility</i>	36	43	50	29	22
<i>Change in Bed Capacity</i>	136	54	48	25	38
<i>Covered Clinical Services</i>	160	163	237	145	133
<i>Covered Capital Expenditures</i>	58	53	66	43	38
Disapproved					
<i>Acquire, Begin, or Replace a Health Facility</i>	2	23	1	0	0
<i>Change in Bed Capacity</i>	2	28	2	1	0
<i>Covered Clinical Services</i>	0	1	0	0	0
<i>Covered Capital Expenditures</i>	1	25	2	1	0

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
FY2020 - FY2024

	Approved	Approved with Conditions	Disapproved	Totals
Number of Final Decisions				
FY2020	147	167	2	316
FY2021	168	90	29	287
FY2022	186	68	2	256
FY2023	162	35	1	198
FY2024	161	29	0	190
Total Project Costs				
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
FY2023	\$776,646,425	\$176,587,049	\$6,346,626	\$959,580,100
FY2024	\$2,655,918,377	\$117,791,965	\$0	\$2,733,710,342

Note: Final decisions include emergency CON applications.

In FY2024, there were no CON applications that received a final decision of disapproval from the Department.

CERTIFICATE OF NEED ACTIVITY SUMMARY COMPARISON

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

TABLE 11 CON ACTIVITY COMPARISON FY2020 - FY2024				
	Number of Applications	Difference from Previous Year	Total Project Costs	Difference from Previous Year
Letters of Intent Processed				
FY2020	420	15%	\$1,861,451,187	(35%)
FY2021	396	(6%)	\$2,443,097,718	31%
FY2022	300	(24%)	\$1,845,302,652	(24%)
FY2023	301	0.3%	\$3,531,890,321	91%
FY2024	254	(16%)	\$1,103,763,893	(69%)
Applications Submitted				
FY2020	339	61%	\$2,507,922,695	3%
FY2021	309	(9%)	\$1,703,931,501	(32%)
FY2022	255	(17%)	\$2,321,037,942	36%
FY2023	201	(21%)	\$1,159,033,442	(50%)
FY2024	192	(4%)	\$2,787,870,974	41%
Final Decisions Issued				
FY2020	316	40%	\$2,339,039,880	75%
FY2021	288	(9%)	\$1,944,965,809	(17%)
FY2022	287	(.03%)	\$2,517,447,509	29%
FY2023	198	(31%)	\$960,425,600	(62%)
FY2024	197	(0.5%)	\$2,797,161,789	91%

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
FY2020 - FY2024

	FY2020	FY2021	FY2022	FY2023	FY2024
<i>Amendments Received</i>	57	57	74	66	66
<i>Amendment Decisions Issued</i>	66	57	61	80	60
<i>Percent Issued within Required Time Frame</i>	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 2024. Fifty-one (51) of the 190 CON approvals in FY 2024 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
FY2024

Covered Clinical Services/Beds	Existing Sites	Existing Units/Beds	New Sites	New Units/Beds
Air Ambulances	11	26	0	0
Cardiac Catheterization Services	57	235	1	4
Primary PCI	3	N/A	0	N/A
Elective PCI	16	N/A	0	N/A
Open Heart Surgical Services	*34	N/A	0	N/A
Surgical Services	279	1552	8	42
CT Scanners Services	259	399	8	4
MRI Services	351	265	3	2
PET Services	102	33	0	1
Lithotripsy Services	90	11	3	0
MRT Services	70	128	0	0
Transplant Services	6	N/A	0	N/A
Hospitals	161	24,869	0	192
NICU Services	21	654	0	0
SCN Services	14	111	0	0
Extended Care Services Program (Swing Beds)	44	413	0	0
Nursing Homes/HLTCU	443	45,438	0	0
Psychiatric Hospitals/Units	58	3,727	3	179
Psychiatric Flex Beds	4	72	0	24

Note: The source for the existing site and unit/bed information for Table 13 was the 2023 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 2024. New sites include LTAC Hospitals; mobile host sites for CT, Lithotripsy, MRI and PET services; & Psychiatric data includes special pool beds.

**One OHS hospital received approval to become a primary & elective PCI service provider without on-site OHS.*

COMPLIANCE ACTIONS

Table 14 shows there were 203 projects requiring follow-up for FY 2024 based on the Department's Monthly Follow-up/Monitoring Report as shown below.

TABLE 14 FOLLOW UP AND COMPLIANCE ACTIONS FY2020 - FY2024					
	FY2020	FY2021	FY2022	FY2023	FY2024
<i>Projects Requiring 1-yr Follow-up</i>	225	314	261	264	203
<i>Approved CONs Expired</i>	87	95	62	204	73
<i>Compliance Orders Issued</i>	65	95	26	47	23

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 CON-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 conducted statewide compliance reviews for Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services, Neonatal Intensive Care Services/Beds (NICU) Services, and Special Newborn Nursing (SCN) Services. All finalized compliance actions resulting from the statewide compliance reviews will be reflected within the FY 2025 annual report.

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	
<u>Total Project Costs</u>	<u>CON Application Fee</u>
\$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
<u>Additional Fee Category</u>	<u>Additional Fee</u>
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 FY2020 – FY2024					
CON Fee	FY2020	FY2021	FY2022	FY2023	FY2024
\$ 0*	106	32	21	6	4
\$3,000	78	84	77	81	76
\$8,000	79	101	64	63	61
\$11,000	25	58	36	21	29
\$15,000	53	34	57	30	20
TOTAL	341	309	255	201	190

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 FY2020 – FY2024					
CON Fee Category	FY2020	FY2021	FY2022	FY2023	FY2024
Complex Project	36	7	5	5	2
Expedited Review	41	26	12	39	28
LOI Waiver*	45	37	53	63	51
Amendment*	57	57	74	66	66
Annual Survey (Facilities)	1067	1094	1091	1087	1099

**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 FY2020– FY2024					
	FY2020*	FY2021	FY2022	FY2023	FY2024
Program Cost	\$2,109,705	\$2,463,147	\$2,348,344	\$2,220,542	\$2,262,405
Fees/Funding	\$2,447,531	\$2,520,217	\$2,204,660	\$1,953,109	\$1,583,572
Fees % of Costs	100%+	100%+	94%	88%	70%

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 FY2024, the CON Commission deregulated the Air Ambulance review standards as well as revised the review standards for Computed Tomography (CT) Scanner Services, Psychiatric Beds and Services, Nursing Home and Hospital Long-Term-Care Unit (NH-HLTUCU) Beds, Open Heart Surgery (OHS) Services, Hospital Beds, and Megavoltage Radiation Therapy (MRT).

Regulation for Air Ambulance Services began in the Bureau of EMS Trauma and Preparedness rule set 325.22101 through 325.22218, effective May 26, 2023. The CON Review Standards for Air Ambulance Services were deregulated by the CON Commission effective on February 26, 2024.

The revisions to the CON Review Standards for Computed Tomography (CT) Scanner Services received final approval by the CON Commission on December 7, 2023, and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took negative action within 45 days; therefore, the revisions became effective February 26, 2024. The final language changes include the following:

- 1. Section 2(1): Modified/added definitions as follows:
 - (j) "CT equivalents" OR "CTE" means the resulting number of units produced when the number of billable procedures for each category is multiplied by its respective conversion factor tabled in Section 16.
 - (k) "CT scanner" means x-ray CT scanning systems capable of performing CT scans of the head, other body parts, or full body patient procedures including Positron Emission Tomography (PET)/CT scanner hybrids if used for CT only procedures. The term does not include emission-computed tomographic systems utilizing internally administered single- photon gamma ray emitters, positron annihilation CT systems, magnetic resonance, ultrasound computed tomographic systems, CT simulators used solely
 - for treatment planning purposes in conjunction with an MRT unit, non-diagnostic, intra-operative guidance tomographic units, and dental CT scanners that generate a peak power of 5 kilowatts or less as certified by the manufacturer and are specifically designed to generate CT images to facilitate dental procedures by a licensed dentist under the practice of dentistry ONLY. ANY OTHER USE OF CT SCANNERS (SUCH AS BUT NOT LIMITED TO CHIROPRACTIC UTILIZATION) THAT GENERATE A PEAK POWER OF 5 KILOWATTS OR LESS AS CERTIFIED BY THE MANUFACTURER WILL REQUIRE REVIEW AND APPROVAL AS A CT SCANNER SERVICE UNDER APPLICABLE SECTIONS OF THESE STANDARDS. (gg) "REFERRING LICENSED HEALTHCARE PROFESSIONAL" MEANS: (I) THE DOCTOR OF RECORD WHO ORDERED THE CT PROCEDURE(S) AND EITHER TO WHOM THE PRIMARY REPORT OF THE RESULTS OF AN CT PROCEDURE(S) IS SENT, OR IN THE CASE OF A TEACHING FACILITY, THE ATTENDING DOCTOR WHO IS RESPONSIBLE FOR THE HOUSE OFFICER OR RESIDENT THAT REQUESTED THE CT PROCEDURE; OR (II) A NON-PHYSICIAN LICENSED HEALTHCARE PROFESSIONAL ACTING WITHIN THE SCOPE OF THEIR PRACTICE.
 - (hh) "RENEWAL OF LEASE" MEANS EXTENDING THE EFFECTIVE PERIOD OF A LEASE FOR AN EXISTING CT SCANNER THAT DOES NOT INVOLVE EITHER REPLACEMENT OF THE CT SCANNER, AS DEFINED IN SECTION 5, OR A CHANGE IN THE PARTIES TO THE LEASE.

- (ii) "Replace an existing CT scanner" means an equipment change of an existing CT scanner, that requires a change in the radiation safety certificate, proposed by an applicant which results in that applicant operating the same number of CT scanners before and after project completion, at the same geographic location. The term also includes relocating an existing CT scanner or CT scanner service from an existing site to a different site; AND RENEWAL OF LEASE.
- 2. Section 5: Added language for lease renewal, similar to MRI Services:
 - Sec. 5. An applicant proposing to replace an existing CT scanner or service, OR RENEW THE LEASE OF AN EXISTING CT SCANNER, other than a hospital-based portable CT scanner service, shall demonstrate the following, as applicable:
 - (1) An applicant proposing to replace an existing fixed, mobile, or dedicated pediatric CT scanner shall demonstrate all of the following:
 - (a) The replacement CT scanner will be located at the same site as the CT scanner to be replaced.
 - (b) AN APPLICANT PROPOSING TO REPLACE AN EXISTING CT SCANNER THAT DOES NOT INVOLVE A RENEWAL OF A LEASE SHALL DEMONSTRATE THAT the existing CT scanner(s) proposed to be replaced is fully depreciated according to generally accepted accounting principles, or, that the existing equipment clearly poses a threat to the safety of the public, or, that the proposed replacement CT scanner offers technological improvements which enhance quality of care, increase efficiency, and/or reduce operating costs and patient charges.
- 3. Section 17: Added language that prohibits the withdrawal of CT physician commitment during the application review process.
 - (1) An applicant required to project under Section 3 shall demonstrate that the projection is based on historical REFERRING LICENSED HEALTHCARE PROFESSIONAL physician referrals that resulted in an actual scan for the most recent 12-month period immediately preceding the date of the application. Historical physician referrals will be verified with the data maintained by the Department through its "Annual Hospital statistical survey" and/or "Annual Freestanding Statistical Survey."
 - (2)(a) A written commitment from each referring LICENSED HEALTHCARE PROFESSIONAL physician that he or she will refer at least the volume of CT scans to be transferred to the proposed CT scanner service for no less than 3 years subsequent to the initiation of the CT scanner service proposed by an applicant.
 - (2)(b) The number of referrals committed must have resulted in an actual CT scan of the patient at the existing CT scanner service from which referral will be transferred. The committing REFERRING LICENSED HEALTHCARE PROFESSIONAL physician must make available HIPAA compliant audit material if needed upon Department request to verify referral sources and outcomes. Commitments must be verified by the most recent data set maintained by the Department through its "Annual Hospital Statistical Survey" and/or "Annual Freestanding Statistical Survey."
 - (3) THE DEPARTMENT SHALL NOT CONSIDER A WITHDRAWAL OF A SIGNE DATA COMMITMENT ON OR AFTER THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT.
 - (4) THE DEPARTMENT SHALL CONSIDER A WITHDRAWAL OF A SIGNED DATA COMMITMENT IF A COMMITTING DOCTOR SUBMITS A WRITTEN NOTICE TO THE DEPARTMENT BEFORE THE APPLICATION IS DEEMED

SUBMITTED, THAT SPECIFIES THE CON APPLICATION NUMBER AND THE SPECIFIC CT SERVICES FOR WHICH A DATA COMMITMENT IS BEING WITHDRAWN.

- 4. Section 14(4) Added subsection to require a notification to the Department no later than 30 days after a planned decrease or discontinuation of services:
 - (e) THE APPLICANT SHALL PROVIDE NOTICE TO THE DEPARTMENT OF ANY PLANNED DECREASE OR DISCONTINUATION OF SERVICE(S) NO LATER THAN 30 DAYS AFTER THE PLANNED DECREASE OR DISCONTINUATION OF THE SERVICE(S).
- 5. Other technical edits.

The revisions to the CON Review Standards for Psychiatric Beds and Services received final approval by the CON Commission on December 7, 2023, and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took negative action within 45 days; therefore, the revisions became effective February 26, 2024. The final language changes include the following:

- 1. Section 13(4): Added subsection to require a notification to the Department at least 30 days prior to a planned decrease or discontinuation of services:
 - (g) THE APPLICANT SHALL PROVIDE NOTICE TO THE DEPARTMENT OF ANY PLANNED DECREASE OR DISCONTINUATION OF SERVICE(S) NO MORE THAN 30 DAYS AFTER THE PLANNED DECREASE OR DISCONTINUATION OF THE SERVICE(S).
- 2. New Section 15: Added language to create a pilot program for child and adolescent psychiatric beds that will allow for applicants to acquire beds without utilizing bed need methodology:
 - SECTION 15. PILOT PROGRAM REQUIREMENTS FOR APPLICANTS PROPOSING TO INITIATE OR INCREASE CHILD AND ADOLESCENT PSYCHIATRIC BEDS SEC. 15. (1) AN APPLICANT PROPOSING THE INITIATION OF A CHILD/ADOLESCENT PSYCHIATRIC SERVICE SHALL DEMONSTRATE OR PROVIDE THE FOLLOWING:
 - (a) A WRITTEN RECOMMENDATION, FROM THE DEPARTMENT OR THE CMH THAT SERVES THE COUNTY IN WHICH THE PROPOSED BEDS OR SERVICES WILL BE LOCATED, SHALL INCLUDE AN AGREEMENT TO ENTER INTO A CONTRACT TO MEET THE NEEDS OF THE PUBLIC PATIENT. AT A MINIMUM, THE LETTER OF AGREEMENT SHALL SPECIFY THE NUMBER OF BEDS TO BE ALLOCATED TO THE PUBLIC PATIENT AND THE APPLICANT'S INTENTION TO SERVE PATIENTS WITH AN INVOLUNTARY COMMITMENT STATUS.
 - (b) THE NUMBER OF BEDS PROPOSED IN THE CON APPLICATION TO BE ALLOCATED FOR USE BY THE PUBLIC PATIENTS SHALL NOT BE LESS THAN 50% OF THE BEDS PROPOSED IN THE CON APPLICATION.
 - (c) THE MINIMUM NUMBER OF BEDS IN A PSYCHIATRIC UNIT SHALL BE AT LEAST 10 BEDS. THE DEPARTMENT MAY APPROVE AN APPLICATION FOR A UNIT OF LESS THAN 10 BEDS, IF THE APPLICANT DEMONSTRATES TO THE SATISFACTION OF THE DEPARTMENT, THAT TRAVEL TIME TO EXISTING UNITS WOULD SIGNIFICANTLY LIMIT ACCESS TO CARE.
 - (2) AN APPLICANT PROPOSING AN INCREASE OF CHILD/ADOLESCENT PSYCHIATRIC BEDS SHALL DEMONSTRATE OR PROVIDE THE FOLLOWING:

- (a) AN APPLICANT MAY APPLY FOR THE ADDITION OF NEW CHILD/ADOLESCENT PSYCHIATRIC BEDS IF BEDS ARE BEING ADDED AT THE EXISTING LICENSED SITE. FURTHER, AN APPLICATION PROPOSING NEW BEDS AT AN EXISTING LICENSE PSYCHIATRIC HOSPITAL OR UNIT SITE SHALL AGREE AND ASSURE COMPLIANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS, EXCLUDING OCCUPANCY REQUIREMENTS.
- (b) PROOF OF CURRENT CONTRACT OR DOCUMENTATION OF CONTRACT RENEWAL, IF CURRENT CONTRACT IS UNDER NEGOTIATION, WITH AT LEAST ONE CMH OR ITS DESIGNEE THAT SERVES THE PLANNING AREA IN WHICH THE PROPOSED BEDS OR SERVICE WILL BE LOCATED.
- (c) PREVIOUSLY MADE COMMITMENTS, IF ANY, TO THE DEPARTMENT OF CMH TO SERVE PUBLIC PATIENTS HAVE BEEN FULFILLED.
- (d) THE MINIMUM NUMBER OF BEDS IN A PSYCHIATRIC UNIT SHALL BE AT LEAST 10 BEDS. THE DEPARTMENT MAY APPROVE AN APPLICATION FOR A UNIT OF LESS THAN 10 BEDS, IF THE APPLICANT DEMONSTRATES, TO THE SATISFACTION OF THE DEPARTMENT, THAT TRAVEL TIME TO EXISTING UNITS WOULD SIGNIFICANTLY IMPAIR ACCESS TO CARE.
- (3) AN APPLICANT UNDER THIS SECTION SHALL DEMONSTRATE THAT IT MEETS THE REQUIREMENTS OF SECTION 12.
- (4) AN APPLICANT UNDER THIS SECTION SHALL DEMONSTRATE THAT IT MEETS THE REQUIREMENTS OF SECTION 13.
- (5) AN APPLICANT UNDER THIS SECTION SHALL DEMONSTRATE THAT IT MEETS THE REQUIREMENTS OF SECTION 14.
- (6) AN APPLICANT PROPOSING THE REPLACEMENT OF A CHILD/ADOLESCENT PSYCHIATRIC BED UNDER THIS SECTION SHALL DEMONSTRATE THAT IT MEETS THE REQUIREMENTS OF SECTION 6.
- (7) AN APPLICANT PROPOSING THE ACQUISITION OF A CHILD/ADOLESCENT PSYCHIATRIC SERVICE UNDER THIS SECTION SHALL DEMONSTRATE THAT IT MEETS THE REQUIREMENTS OF SECTION 10.
- (8) THE APPLICANT SHALL NOT RELOCATE ANY CHILD/ADOLESCENT PSYCHIATRIC BEDS APPROVED UNDER THIS SECTION PRIOR TO SEPTEMBER 30, 2030, AND PRIOR TO THE CHILD/ADOLESCENT BEDS BEING LICENSED AND OPERATIONAL. AN APPLICANT MUST DEMONSTRATE THAT IT MEETS THE REQUIREMENTS OF SECTION 7.
- (9) AN APPLICANT UNDER THIS SECTION SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE NEEDED PSYCHIATRIC HOSPITAL BED SUPPLY IF THE APPLICATION MEETS ALL OTHER APPLICABLE CON REVIEW STANDARDS AND AGREES AND ASSURES TO COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS.
- (10) AN APPLICANT UNDER THIS SECTION SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW.
- (11) IF THE COMMISSION DOES NOT TAKE ACTION TO EXTEND THE DURATION OF THE PILOT PROGRAM DESCRIBED IN THIS SECTION BY JULY 1, 2030, ALL OF THE FOLLOWING MUST OCCUR:
 - (a) THE PROVISIONS OF THIS SECTION SHALL NOT BE APPLICABLE TO ANY APPLICATION SUBMITTED AFTER JULY 1, 2030;
 - (b) THE PROVISIONS OF THIS SECTION WILL EXPIRE ON SEPTEMBER

- 30, 2030;
 - (c) AFTER SEPTEMBER 30, 2030 THE PROVISIONS OF THIS SECTION, EXCLUDING SUBSECTION 11(D) WILL BE OF NO FORCE AND EFFECT; AND
 - (d) ANY CHILD/ADOLESCENT PSYCHIATRIC BEDS APPROVED UNDER THIS SECTION MUST MEET ALL PROJECT DELIVERY REQUIREMENTS, INCLUDING OCCUPANCY REQUIREMENTS FOLLOWING THE TERMINATION OF THE PILOT PROGRAM DESCRIBED IN THIS SECTION.
 - (12) BY APRIL 30TH OF EACH YEAR, THE APPLICANT SHALL PROVIDE A SEPARATE ANNUAL REPORT TO THE DEPARTMENT REGARDING ALL CHILD/ADOLESCENT PSYCHIATRIC BEDS APPROVED UNDER THIS SECTION FOR THE PRECEDING CALENDAR YEAR, IN A FORMAT ESTABLISHED BY THE DEPARTMENT AND IN A MUTUALLY AGREED UPON MEDIA. THIS REPORTING REQUIREMENT SHALL CONTINUE FOR A PERIOD OF 7 YEARS, OR AS DETERMINED BY THE COMMISSION.
- 3. Addendum Section 1: Modified the definition of a “Medical psychiatric unit” to allow initiation of freestanding medical psychiatric unit and to increase flexibility in the use of medical psychiatric beds:
- (d) “Medical psychiatric unit” means a unit designed for psychiatric patients (adult or child/adolescent as applicable) who have also been diagnosed with a medical illness COMORBIDITY requiring EITHER:
 - (I) ACUTE MEDICAL NURSING INTERVENTION AND MONITORING, OR
 - (II) hospitalization TREATMENT WITH DAILY DIRECTION OR SUPERVISION OF A PHYSICIAN OTHER THAN A PSYCHIATRIST (e.g., patients who may be on dialysis, require wound care or need intravenous or tube feeding) EXCEPT AS FOLLOWS:
 - (i) A MEDICAL PSYCHIATRIC UNIT LOCATED IN A HOSPITAL LICENSED UNDER PART 215 OF THE CODE, MAY BE USED FOR PSYCHIATRIC PATIENTS NOT DIAGNOSED WITH A MEDICAL ILLNESS UP TO A MAXIMUM OF 146 PATIENT DAYS PER YEAR PER BED PURSUANT TO THE LIMITATIONS DETAILED IN SECTION 9(4)(j).
- 4. Addendum Section 6: Modified/added sections to allow for initiation of a freestanding medical psychiatric unit:
- (1)(a)(ii)(E) ACCESS TO SPECIALIST PHYSICIANS FOR CONSULTATION RELATED TO THE TREATMENT OF MEDICAL PSYCHIATRIC PATIENTS.
 - (1)(d) Staff, including contracted staff, will:
 - (i) be specially trained in treatment of medical psychiatric patients;
 - (ii) INCLUDE AN APPROPRIATE NUMBER OF REGISTERED NURSES (RNS) TO CARE FOR THE NUMBER AND ACUITY OF PATIENTS ADMITTED;
 - (iii) INCLUDE A RAPID RESPONSE AND CODE TEAM COMPRISED OF RNS AND ANY OTHER MEDICAL STAFF AVAILABLE ON-SITE; AND
 - (iv) INCLUDE A LICENSED HOSPITAL PROVIDER ON-SITE DAILY AND AVAILABLE 24-HOUR, 365-DAY VIA CALL COVERAGE.
 - (e) The proposed beds will serve only medical psychiatric patients.
 - (f) THE FACILITY AGREES TO PROVIDE AT LEAST THE FOLLOWING MEDICAL SERVICES WHICH DO NOT REQUIRE ACUTE CARE HOSPITAL ADMISSION:
 - (i) ADVANCED WOUND CARE (FOR TREATMENT OF WOUNDS SHOWING SIGNS OF INFECTION THAT REQUIRE TREATMENT BY A MEDICAL DOCTOR OTHER THAN A PSYCHIATRIST); AND
 - (ii) INTRAVENOUS LINE CARE.

- 5. Addendum Section 9: Added language to allow initiation of freestanding medical psychiatric unit and to increase flexibility in the use of medical psychiatric beds:
- (4)(d)(i) Patient admission criteria that describe minimum and maximum characteristics for patients appropriate for admission to the medical psychiatric unit. A UNIT LICENSED ONLY UNDER 1974 PA 278, CHAPTER 1, SHALL CLEARLY INDICATE THE FACILITY WILL NOT ADMIT PATIENTS REQUIRING ACUTE CARE HOSPITAL ADMISSION.
 - (4)(i) THE FACILITY SHALL PROVIDE AT LEAST THE FOLLOWING MEDICAL STAFF AND SERVICES WHICH DO NOT REQUIRE ACUTE CARE HOSPITAL ADMISSION:
 - (i) STAFF SPECIALLY TRAINED IN TREATMENT OF MEDICAL PSYCHIATRIC PATIENTS;
 - (ii) INCLUDE AND APPROPRIATE NUMBER OF REGISTERED NURSES (RNS) TO CARE FOR THE NUMBER AND ACUITY OF PATIENTS ADMITTED;
 - (iii) A RAPID RESPONSE AND CODE TEAM COMPRISED OF RNS AND ANY OTHER MEDICAL STAFF ON-SITE.
 - (iv) INCLUDE A LICENSED HOSPITALIST PROVIDER ON-SITE DAILY AND AVAILABLE 24-HOUR, 365-DAY VIA CALL COVERAGE.
 - (v) ADVANCED WOUND CARE (FOR TREATMENT OF WOUNDS SHOWING SIGNS OF INFECTION THAT REQUIRE TREATMENT BY A MEDICAL DOCTOR OTHER THAN A PSYCHIATRIST); AND
 - (vi) INTRAVENOUS LINE CARE.
 - (j) AN APPLICANT PLACING A PATIENT IN A BED IN A MEDICAL/PSYCHIATRIC UNIT PURSUANT TO SECTION 1(D)(I) MUST FOLLOW THE FOLLOWING PROCEDURES WITH RESPECT TO SUCH PLACEMENT:
 - (i) THE APPLICANT MUST NOT HAVE BEEN ABLE TO PLACE SUCH PATIENT REQUIRING AN INPATIENT PSYCHIATRIC HOSPITAL ADMISSION AT THE TIME OF THE PATIENT'S VISIT TO THE APPLICANT'S EMERGENCY ROOM AT A DIFFERENT INPATIENT PSYCHIATRIC FACILITY WITHIN A 60-MINUTE DRIVE TIME OF THE APPLICANT'S HOSPITAL LOCATION WITHIN 6 HOURS AFTER THE DETERMINATION FOR SUCH NEED FOR INPATIENT PSYCHIATRIC CARE BEING MADE.
 - (ii) THE APPLICANT MUST HAVE ATTEMPTED TO PLACE SUCH PATIENT AT A MINIMUM OF THREE FACILITIES OVER AT LEAST A 6-HOUR PERIOD TO SECURE ADMISSION OF THE PATIENT TO A PSYCHIATRIC HOSPITAL OR UNIT, ALL OF WHICH FAILED DUE TO A LACK OF AVAILABLY PSYCHIATRIC BEDS AT THE OTHER FACILITIES OR DUE TO THE MEDICAL ADMISSION CRITERIA OF THE FACILITIES.
 - (iii) THE APPLICANT MUST SUBMIT VERIFIABLE INFORMATION APPROVED UNDER THIS SECTION FOR THE PRECEDING CALENDAR YEAR, IN A FORMAT ESTABLISHED BY THE DEPARTMENT AND IN A MUTUALLY AGREED UPON MEDIA. THE APPLICANT HAS COMPLIED WITH THE REQUIREMENTS OF SECTIONS 9(4)(j)(i) and 9(4)(j)(ii) FOR EACH PATIENT ADMITTED TO A MEDICAL PSYCHIATRIC BED UNDER SECTION 1(d)(i). SUCH INFORMATION SHALL INCLUDE:
 - (A) THE NUMBER OF REFERRALS PER PATIENT, INCLUDING THE NUMBER OF PATIENTS THAT WERE ADMITTED TO A UNIT DESCRIBED IN THIS SECTION WITH LESS THAN 3 REFERRALS AND THE REASON FOR LESS THAN 3 REFERRALS; AND

- (B) THE REASONS FOR DENIAL OF ADMISSION BY ANOTHER FACILITY FOR EACH PATIENT.
- (C) REQUIRED DOCUMENTATION MUST BE MAINTAINED BY THE APPLICANT AND MADE AVAILABLE UPON REQUEST BY THE DEPARTMENT.
- (4)(k) SECTIONS 1(d)(I), 9(4)(K) SHALL BE SUBJECT TO REVIEW BY THE CON COMMISSION IN 2027.

The revisions to the CON Review Standards for Nursing Home and Longer-Term Care Unit Beds (NH-LTCU) received final approval by the CON Commission on December 7, 2023, and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took negative action within 45 days; therefore, the revisions became effective February 26, 2024. The final language changes include the following:

- 1. Section 7: Added new subsection that requires previously approved change of ownership CON is a completed project before replacement applications can be approved.
 - (4) AN APPLICANT PROPOSING TO REPLACE BEDS MUST DEMONSTRATE THAT ANY PREVIOUSLY APPROVED CHANGE OF OWNERSHIP (CHOW) CERTIFICATE OF NEED FOR THE FACILITY HAS BEEN DEEMED A COMPLETED PROJECT BY THE DEPARTMENT BEFORE THE REPLACEMENT APPLICATION CAN BE APPROVED.
- 2. Section 8: Added new subsection that requires previously approved change of ownership CON is a completed project before relocation applications can be approved.
 - (1)(g) AN APPLICANT PROPOSING TO RELOCATE BEDS, UNDER SECTION 8(1), MUST DEMONSTRATE THAT ANY PREVIOUSLY APPROVED CERTIFICATE OF NEED FOR ADDITION OF EXISTING NURSING HOME/HLTCU BEDS AT THE FACILITY, UNDER SECTION 8(2), HAS BEEN DEEMED A COMPLETED PROJECT BY THE DEPARTMENT BEFORE THE RELOCATION APPLICATION CAN BE APPROVED.
 - (3) AN APPLICANT PROPOSING TO RELOCATE EXISTING NURSING HOME/HLTCU BEDS, UNDER SECTION 8(1), OR ADD EXISTING NURSING HOME/HLTCU BEDS, UNDER SECTION 8(2), MUST DEMONSTRATE THAT ANY PREVIOUSLY APPROVED CHANGE OF OWNERSHIP (CHOW) CERTIFICATE OF NEED FOR THE FACILITY HAS BEEN DEEMED A COMPLETED PROJECT BY THE DEPARTMENT BEFORE THE RELOCATION APPLICATION CAN BE APPROVED.
- 3. Section 9: Modified/added language that requires delinquent debt be paid or an approved payment plan with the Department of Treasury is agreed to and current before an applicant is approved to acquire an existing nursing home or renew the lease of an existing nursing home:
 - ⊖ (3)(d) THE FOLLOWING DELINQUENT DEBT OBLIGATIONS TO THE STATE OF MICHIGAN HAVE BEEN PAID, OR THE APPLICANT IS IN COMPLIANCE WITH A PAYMENT PLAN CONCERNING THE SAME AGREED TO BY THE APPLICANT AND THE MICHIGAN DEPARTMENT OF TREASURY:
 - (i) QUALITY ASSURANCE ASSESSMENT PROGRAM (QAAP),
 - (ii) PREADMISSION SCREENING AND ANNUAL RESIDENT REVIEW (PASARR), AND
 - (iii) CIVIL MONETARY PENALTIES (CMP).
- 4. Section 11: Added subsection to require a notification to the Department at least 30 days prior to a planned decrease or discontinuation of services:

- (c) THE APPLICANT SHALL PROVIDE NOTICE TO THE DEPARTMENT OF ANY PLANNED DECREASE OR DISCONTINUATION OF SERVICE(S) NO LATER THAN 30 DAYS AFTER THE PLANNED DECREASE OR DISCONTINUATION OF THE SERVICE(S).
- 5. Section 11: Added subsection that requires all applicants remain current on taxes, fines, and fees, or that the applicant has an approved payment plan with the Department of Treasury and is current on payments:
 - (6) THE APPLICANT SHALL AGREE THAT, IF APPROVED, IT WILL REMAIN CURRENT ON ALL TAXES, FINES, AND FEES OWED TO THE STATE OF MICHIGAN. A PAYMENT PLAN AGREED UPON BY THE APPLICANT AND THE MICHIGAN DEPARTMENT OF TREASURY SHALL BE CONSIDERED NOT DELINQUENT FOR THE PURPOSE OF THIS SECTION ON THE CONDITION THE APPLICANT IS CURRENT AND REMAINS CURRENT ON PAYMENTS, INCLUDING THE OBLIGATIONS APPLICABLE TO THIS SECTION INCLUDE: QUALITY ASSURANCE ASSESSMENT PROGRAM (QAAP), PREADMISSION SCREENING AND ANNUAL RESIDENT REVIEW (PASARR), AND CIVIL MONETARY PENALTIES (CMP).
- 6. Other technical edits.

The revisions to the CON Review Standards for Open Heart Surgery (OHS) Services received final approval from the CON Commission on March 14, 2024 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took negative action within 45 days; therefore, the revisions became effective May 6, 2024. The final language changes include the following:

- 1. Section 8(4)(d): Revised monitoring and reporting requirements for STS star ratings:
 - (d)The applicant hospital shall participate in a data registry administered by the Department or its designee as a means to measure quality and risk adjusted outcomes within OHS programs. The Department shall use ALL COMPOSITES IN the STS Composite Star Rating System, INCLUDING BUT NOT LIMITED TO: which currently includes coronary artery bypass graft composite (CABG), aortic valve replacement (AVR), AND THE MULTIPROCEDURAL composite MEASURE., and plans to add additional cardiac surgical composites each year. The Department or its designee shall require that the applicant hospital submit a summary report as specified by the Department. The applicant hospital shall provide the required data in a format established by the Department or its designee. The applicant hospital shall be liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. The applicant hospital shall become a member of the data registry specified by the Department upon initiation of the service and continue to participate annually thereafter for the life of that service. The outcomes database must undergo statewide auditing.
- 2. Section 8(4): Revised reporting procedure for STS Composite Star Ratings:
 - (e) The applicant hospital shall utilize and report the STS Composite Star Rating System for all procedures as follows:
 - (i) IF THE PROGRAM DOES NOT QUALIFY TO RECEIVE A STAR RATING IN ONE OR MORE COMPOSITE METRICS BUT RECEIVES A TWO-STAR OR HIGHER RATING IN AT LEAST ONE COMPOSITE METRIC FOR THE SAME TIME PERIOD, THE PROGRAM SHALL BE CONSIDERED IN COMPLIANCE.

- (ii) If the program receives a one-star rating in any composite metric, they shall submit a report to the Department explaining the reason(s) for the unsatisfactory rating.
- (iii) If the program receives two one-star ratings in a row in the same composite metric, they shall submit an action plan to the Department detailing specific actions to rectify the program deficiencies.
- (iv) If the program receives two one-star ratings within the same composite metric, the program may have two years to obtain a minimum two-star rating within that composite metric. Upon receipt of a two-star or higher rating, the program SHALL be considered in compliance.
- (f) IF THE PROGRAM PARTICIPATES IN THE STS COMPOSITE STAR RATING SYSTEM AND DOES NOT RECEIVE A STAR RATING FOR ANY REASON, THEY SHALL SUBMIT A REPORT TO THE DEPARTMENT EXPLAINING THE REASON(S) FOR NOT RECEIVING A STAR RATING.
- 3. Section 8(4): Added subsection to require a notification to the Department at least 30 days prior to a planned decrease or discontinuation of services:
 - (h) THE APPLICANT SHALL PROVIDE NOTICE TO THE DEPARTMENT OF ANY PLANNED DECREASE OR DISCONTINUATION OF SERVICE(S) NO LATER THAN 30 DAYS AFTER THE PLANNED DECREASE OR DISCONTINUATION OF THE SERVICE(S).

The revisions to the CON Review Standards for Hospital Beds received final approval by the CON Commission on March 14, 2024 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took negative action within 45 days; therefore, the revisions became effective May 6, 2024. The final language changes include the following:

- 1. Section 2(1): Updated definitions for “Alcohol and substance abuse hospital” and “Obstetrics patient days of care” to reflect updated MS-DRGs:
 - (c) "Alcohol and substance abuse hospital" means a licensed hospital within a long-term (acute) care (LTAC) hospital that exclusively provides inpatient medical detoxification and medical stabilization and related outpatient services for persons who have a primary diagnosis of substance dependence covered by MS-DRGs –894 - 897. THE DEPARTMENT SHALL UPDATE THE MS-DRGS UTILIZING THE MOST CURRENT MIDB DATA AVAILABLE TO THE DEPARTMENT, AS NEEDED, AND AS FOLLOWS: (I) UPDATES TO THE MS-DRGS SHALL NOT REQUIRE STANDARD ADVISORY COMMITTEE ACTION, A PUBLIC HEARING, OR SUBMITTAL OF THE STANDARD TO THE LEGISLATURE AND GOVERNOR IN ORDER TO BECOME EFFECTIVE. (II) THE DEPARTMENT SHALL NOTIFY THE COMMISSION WHEN THE UPDATES ARE MADE AND THE EFFECTIVE DATE OF THE MS-DRGS.
 - (gg) "Obstetrics patient days of care" means inpatient days of care for patients in the applicant's Michigan Inpatient Data Base data ages 15 AND OVER with MS-DRGs LISTED IN APPENDIX E (obstetrical discharges). THE DEPARTMENT SHALL UPDATE THE MS-DRGS UTILIZING THE MOST CURRENT MIDB DATA AVAILABLE TO THE DEPARTMENT, AS NEEDED, AND AS FOLLOWS: (I) UPDATES TO THE MS-DRGS SHALL NOT REQUIRE STANDARD ADVISORY COMMITTEE ACTION, A PUBLIC HEARING, OR SUBMITTAL OF THE STANDARD TO THE LEGISLATURE AND GOVERNOR IN ORDER TO BECOME EFFECTIVE. (II) THE DEPARTMENT SHALL NOTIFY THE COMMISSION WHEN THE UPDATES ARE MADE AND THE EFFECTIVE DATE OF THE MS-DRGS.

- 2. Modified Section 6: Added language allowing continued operation for an LTAC or IRF hospital after closure of host hospital:
 - Section 6. Requirements for approval -- new beds in a hospital, LTAC HOSPITAL OR IRF HOSPITAL OR SUBSTANCE ABUSE HOSPITAL; RELICENSURE OF BEDS BY A HOST HOSPITAL; LTAC OR IRF HOSPITAL SPACE RENEWAL OF LEASE; AND LTAC OR IRF HOSPITAL CONTINUED OPERATION AFTER HOST HOSPITAL CLOSES
 - (2) An applicant proposing to begin operation as a new LTAC hospital, IRF hospital, or alcohol and substance abuse hospital within an existing licensed, host hospital, OR AN LTAC OR IRF HOSPITAL CONTINUING OPERATION AFTER A HOST HOSPITAL CLOSES, shall demonstrate that it meets all of the requirements of this subsection:
 - (iii) That upon non-renewal and/or termination of the lease, upon termination of the license issued under Part 215 of the act to the applicant for the new hospital, or upon noncompliance with the project delivery requirements, UPON VOLUNTARY CLOSURE OF THE HOST HOSPITAL, or any other applicable requirements of these standards, the beds licensed as part of the new hospital must be disposed of by one of the following means:
 - (D) VOLUNTARY CLOSURE OF THE HOST HOSPITAL. AN LTAC or IRF HOSPITAL PROPOSING TO CONTINUE OPERATION AFTER ITS HOST HOSPITAL VOLUNTARILY CLOSES SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW AND SHALL BE PROCESSED UNDER THE SAME PROCEDURES FOR NON-SUBSTANTIVE REVIEW. THE APPLICANT SHALL ALSO DEMONSTRATE IT MEETS ALL OF THE FOLLOWING:
 - (1) THE LTAC OR IRF HOSPITAL HAS OR AGREES TO PERMANENTLY ACQUIRE ITS LTAC OR IRF HOSPITAL BEDS FROM THE HOST HOSPITAL AS DEMONSTRATED BY A CURRENT AGREEMENT WITH THE HOST HOSPITAL OR OTHER DOCUMENTATION ACCEPTABLE TO THE DEPARTMENT,
 - (2) THE LTAC OR IRF HOSPITAL HAS OR AGREES THAT IT WILL HAVE CONTINUED CONTROL OF ITS PHYSICAL SPACE AS DEMONSTRATED BY A CURRENT EXECUTED LEASE, PROOF OF OWNERSHIP, AN AGREEMENT TO LEASE OR PURCHASE OR OTHER DOCUMENTATION ACCEPTABLE TO THE DEPARTMENT,
 - (3) THE LTAC OR IRF AGREES TO COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS, AND
 - (4) THE LTAC OR IRF HOSPITAL APPROVED UNDER THIS SUBSECTION AGREES THAT IF IT CEASES OPERATION AS AN LTAC OR IRF HOSPITAL IT WILL DISPOSE OF ITS LICENSED BEDS BY EITHER
 - (i) RELOCATING THE BEDS TO AN EXISTING, LICENSED HOSPITAL OR
 - (ii) DELICENSING THE BEDS.
- 3. Section 9: Added project delivery requirements for freestanding LTAC or IRF hospital after closure of host hospital:
 - (6) AN LTAC or IRF HOSPITAL APPROVED PURSUANT TO SECTION 6(2) MAY CONTINUE TO OPERATE AFTER ITS HOST HOSPITAL CLOSES AND SHALL BE IN COMPLIANCE WITH ALL OF THE FOLLOWING:
 - (a) BE SEPARATELY LICENSED,
 - (b) MAINTAIN ITS OWN GOVERNING BODY,
 - (c) OWN AND OPERATE ITS APPROVED BEDS, AND
 - (d) OPERATIONS MUST CONTINUE WITHOUT INTERRUPTION INCLUDING MAINTAINING ITS OWN STAFF, SUPPLIES, AND SERVICES.

- 4. Added APPENDIX E to house Obstetrics MSDRGs which will be updated as MIDB data becomes available.
- 5. Section 9(4): Added subsection to require a notification to the Department no later than 30 days after a planned decrease or discontinuation of services:
 - (f) THE APPLICANT SHALL PROVIDE NOTICE TO THE DEPARTMENT OF ANY PLANNED DECREASE OR DISCONTINUATION OF SERVICE(S) NO LATER THAN 30 DAYS AFTER THE PLANNED DECREASE OR DISCONTINUATION OF THE SERVICE(S).

The revisions to the CON Review Standards for Megavoltage Radiation Therapy (MRT) Services/Units received final approval by the CON Commission on June 13, 2024 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took negative action within 45 days; therefore, the revisions became effective September 27, 2024. The final language changes include the following:

- 1. Section 3(3)(c): Reduced distance requirement between MRT services in HSA 8:
 - (c) The site of the proposed MRT service is ~~90~~ 45 driving miles or more, verifiable by the department, from the nearest MRT service.
- 2. Section 10(4): Modified Table 1 equivalent treatment visits and associated definitions:

TABLE 1
Equivalent Treatments

Treatment Visit Category	Non-Special Visit Weight	Special Visit Weight
Simple	.66	
Intermediate	1.00	
Complex	2.00	
IMRT	1.66	
Total Body Irradiation	5.00	5.00
HMRT Therapy		3.33
Stereotactic radiosurgery/radiotherapy*	4.00	4.00
IORT		20.00
VIRTUAL OR ELECTRON SIMULATION	1.00	1.00
*ADDITIONAL ISOCENTER	1.33	1.33
ADDITIVE FACTOR CATEGORY	NON-SRS-SBRT VISIT	SRS/SBRT VISIT
GATING OR INTERNAL TRACKING W/ BEAM HOLD	1.00	1.00
NON-STANDARD IMAGE GUIDANCE	0.50	0.50
IN-ROOM CONTRAST OR TRACER INJECTION	0.25	0.25
IN-ROOM ADAPTIVE TREATMENT PLAN	0.50	0.50

All patients under 5 years of age receive a 2.00 additive factor.

GATING OR INTERNAL TRACKING WITH BEAM HOLD IS THE CONTINUOUS CAPTURING AND MONITORING OF A TARGET, FIDUCIAL, OR A SURROGATE

THAT IS SYNCHRONIZED WITH THE PATIENT'S RESPIRATORY OR ORGAN MOTION DURING RADIATION TREATMENT WITH MODULATION OF THE RADIATION BEAM TO DELIVER RADIATION MORE PRECISELY TO THE TARGET AND/OR DECREASE THE RADIATION DOSE TO THE SURROUNDING NORMAL TISSUE.

GATING OR INTERNAL TRACKING WITH BEAM HOLD IS NOT TO EXCEED ONCE PER MRT TREATMENT VISIT.

~~Gating receives a 1.00 additive factor. Gating is the capturing and monitoring of the target's or fiducial's motion during radiation treatment and the modulation of the radiation beam in order to more precisely deliver radiation to the target and/or decrease the radiation dose to the surrounding normal tissue.~~

NON-STANDARD IMAGE GUIDANCE IS THE PROCESS OF ACQUIRING AND UTILIZING AN INTERNAL ANATOMICAL IMAGING MODALITY WITH THE OBJECTIVE OF GUIDING IMAGES, TAKING PLACE EXCLUSIVELY WITHIN THE DESIGNATED MRT TREATMENT ROOM, AS DELINEATED BELOW. THE FOLLOWING TECHNIQUES SHALL BE CLASSIFIED AS NON-STANDARD IMAGE GUIDANCE: 1) 4DCT, 2) 3D MR IMAGING, AND 3) 3D GAMMA-RAY IMAGING. THESE AFOREMENTIONED IMAGING TECHNIQUES ARE DEEMED TO FALL WITHIN THE SCOPE OF NON-STANDARD IMAGE GUIDANCE. THIS SHOULD TAKE PLACE DURING AN MRT TREATMENT VISIT.

NON-STANDARD IMAGE GUIDANCE IS NOT TO EXCEED ONCE PER MRT TREATMENT VISIT.

~~MR-guided real time tracking radiation w/o adaptive receives a 2.00 additive factor. MR-guided real time tracking radiation w/o adaptive means a visit involving an integrated MRI/MRT unit providing MR images in the treatment room before and during an MRT treatment of any complexity.~~

~~CT-guided real time tracking radiation w/o adaptive receives a 1.00 additive factor. CT-guided real time tracking radiation w/o adaptive means a visit involving an integrated CT/MRT unit providing CT images in the treatment room before and during an MRT treatment of any complexity.~~

IN-ROOM CONTRAST OR TRACER INJECTION IS THE INTRAVENOUS INJECTION OF A CONTRAST AGENT OR TRACER WHILE THE PATIENT IS IN THE MRT TREATMENT ROOM AND DURING AN MRT TREATMENT VISIT.

IN-ROOM CONTRAST OR TRACER INJECTION IS NOT TO EXCEED ONCE PER MRT TREATMENT VISIT.

IN-ROOM ADAPTIVE TREATMENT PLAN SIGNIFIES A DISTINCT VISIT WHEREIN A THREE-DIMENSIONAL (3D) DATASET IS ACQUIRED WITHIN THE MRT TREATMENT ROOM JUST PRIOR TO THE COMMENCEMENT OF AN MRT VISIT. SAID ACQUIRED IMAGES ARE SUBSEQUENTLY UTILIZED TO GENERATE AND EVALUATE AN ORIGINAL RADIATION THERAPY PLAN, WHILE THE PATIENT REMAINS PRESENT WITHIN THE TREATMENT ROOM. THE RESULTANT ADAPTIVE TREATMENT PLAN, REGARDLESS OF ITS CLINICAL IMPLEMENTATION

OR THE UTILIZATION OF THE STANDARD PLAN, IS REQUIRED TO UNDERGO A DOCUMENTED ASSESSMENT BY A PHYSICIAN PRIOR TO THE INITIATION OF MRT TREATMENT, FOR IT TO BE CONSIDERED AND ACCOUNTED FOR.

IN-ROOM ADAPTIVE TREATMENT PLAN IS NOT TO EXCEED ONCE PER MRT TREATMENT VISIT.

~~MR-guided real time tracking radiation with adaptive receives a 3.00 additive factor. MR-guided real time tracking radiation with adaptive means a visit involving an integrated MRI/MRT unit providing MR images in the treatment room before and during an MRT treatment of any complexity; along with creation, evaluation and delivery of a new radiation therapy plan while the patient remains in the treatment room.~~

~~CT-guided real time tracking radiation with adaptive receives 3.00 additive factor. CT-guided real time tracking radiation with adaptive means a visit involving an integrated CT/MRT unit providing CT images in the treatment room before and during an MRT treatment of any complexity; along with creation, evaluation and delivery of a new radiation therapy plan while the patient remains in the treatment room.~~

VIRTUAL OR ELECTRON SIMULATION REFERS TO A SESSION PRIOR TO THE COMMENCEMENT OF AN MRT COURSE, WHEREIN A PATIENT IS POSITIONED WITHIN AN MRT TREATMENT ROOM IN ACCORDANCE WITH PREDETERMINED TREATMENT PARAMETERS, SIMULATING THE CONDITIONS AS IF THE PATIENT WERE TO UNDERGO A PLANNED TREATMENT, WITHOUT THE ACTUAL ADMINISTRATION OF TREATMENT.

VIRTUAL OR ELECTRON SIMULATION IS NOT TO EXCEED TWICE PER COURSE OF TREATMENT.

*ADDITIONAL ISOCENTER IS DEFINED AS EACH ADDITIONAL UNIQUE SET OF TREATMENT BEAMS DESIGNED TO TARGET ONE OR MORE ADDITIONAL LESIONS. THERE IS A MAXIMUM OF FIVE VISITS PER COURSE OF TREATMENT. AFTER THE FIRST ISOCENTER, EACH ADDITIONAL ISOCENTER RECEIVES 1.33 EQUIVALENT TREATMENT VISITS.

Patient specific QA for IMRT receives a 2.0 additive factor, not to exceed twice per course of treatment. Patient specific QA for IMRT means verification of radiation delivered dose and/or fluence through physical measurement with a dosimetry phantom and/or detector array in the treatment room. Prior to the start of treatment and using all of the parameters of the patient's treatment plan, one or more points in the delivered distribution should be compared against the planned distribution.

Patient specific QA for SRS/SBRT receives a 3.0 additive factor, not to exceed twice per course of treatment. Patient specific QA for SRS/SBRT means verification of radiation delivered dose and/or fluence through physical measurement with a dosimetry phantom and/or detector array in the treatment room. Prior to the start of treatment and using all of the parameters of the patient's treatment plan, one or more points in the delivered distribution should be compared against the planned distribution.

~~* After the first isocenter, each additional isocenter receives 1.33 equivalent treatment visits. There is a maximum of five visits per course of therapy.~~

- 3. Section 11(4): Added subsection to require a notification to the Department no later than 30 days after a planned decrease or discontinuation of services:
 - (f) THE APPLICANT SHALL PROVIDE NOTICE TO THE DEPARTMENT OF ANY PLANNED DECREASE OR DISCONTINUATION OF SERVICE(S) NO LATER THAN 30 DAYS AFTER THE PLANNED DECREASE OR DISCONTINUATION OF THE SERVICE(S).

The following review standards were reviewed with anticipated completion in FY2025:

Hospital Beds: The Commission took Final action at its September 19, 2024 meeting. The standards were sent to the JLC and Governor for a 45-day review (with at least 9 legislative session days), with anticipation to become effective in FY2025.

Bone Marrow Transplantation (BMT) Services: The Commission took Final action at its September 19, 2024 meeting. The standards were sent to the JLC and Governor for a 45-day review (with at least 9 legislative session days), with anticipation to become effective in FY2025.

Surgical Services: The Commission took Final action at its September 19, 2024 meeting. The standards were sent to the JLC and Governor for a 45-day review (with at least 9 legislative session days), with anticipation to become effective in FY2025.

Cardiac Catheterization Services are being reviewed by a SAC.

Magnetic Resonance Imaging (MRI) Services are being reviewed by an informal workgroup.

Heart, Lung, and Liver (HLL) Transplantation Services will be reviewed by a SAC in FY2025.

Psychiatric Beds and Services will be reviewed by an informal workgroup in FY2025.

An informal workgroup will be formed in FY2025 to review the County Designation requirements throughout 11 of the 14 review standards.

APPENDIX I - CERTIFICATE OF NEED COMMISSION

James B. Falahee, Jr., JD, CON Commission Chairperson
Amy Milewski, MD, CON Commission Vice Chairperson
Amy Engelhardt-Kalbfleisch, DO
Eric Ferguson, MD
Debra Guido-Allen, RN
Ashok Kondur, MD
Renee Turner-Bailey
Archie Drake
Greg Salwin
Daniel Velez
Mark DeLano, MD

For a list and contact information of the current CON Commissioners, please visit our website at Michigan.gov/con.