

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES
CERTIFICATE OF NEED (CON) PROGRAM
ANNUAL ACTIVITY REPORT

October 2024 through September 2025
(FY2025)



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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 37th report to the Commission and covers the period beginning Oct 1, 2024, through Sep 30, 2025 (FY2025). 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 (PPOS) 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 use 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 compliance with the terms and conditions of approvals.

During FY2025, the Department has continued to make process improvements in both the Policy and Evaluation Sections.

The CON Evaluation Section launched and enhanced the recorded instructional aids for the Annual Survey online system to assist health care providers in understanding the survey reporting requirements and completing the health facility surveys. The Department completed statewide compliance review of all facilities providing Open-Heart Surgery (OHS) and Positron Emission Tomography (PET) Scanner services. The CON Evaluation Section also facilitated webinars to provide up-to-date information on revised CON standards, application processes and CON annual survey reporting requirements.

The Commission and Special Projects (CASP) 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.

- **Hospital Beds Review Standards:** Added a definition and updated the standards to account for rural emergency hospitals (REH); changes went into effect in FY2025.
- **Surgical Services Review Standards:** Updated to incorporate access for dialysis and rural hospitals, and several sections were clarified. Changes effective during FY2025.
- **Bone Marrow Transplantation (BMT) Services:** There were minimal technical updates to the review standards that were effective during FY2025.
- **Cardiac Catheterization:** The review standards were modified to allow for Hybrid Operating Room (OR)/Cardiac Catheterization laboratories in facilities other than those with OHS onsite as well as for certain cardiac catheterization procedures to be performed within hospitals without on-site OHS. In addition, language was added to consider cardiac catheterization services in rural areas. Changes were effective during FY2025.
- **Magnetic Resonance Imaging (MRI) Services:** Added language considering Rural and Micropolitan statistical areas. In addition, clarified the terminology for immediately available within the project delivery requirements. The MRI procedure adjustments section was

modified to factor patients with implants or metallic foreign bodies. The changes were effective during FY2025.

- **Urinary Extracorporeal Shock Wave Lithotripsy (UESWL):** Minimal technical edits were made to include renewal of lease as defined in section 2. The changes were effective during FY2025.
- **Psychiatric Beds and Services:** Changes were made during FY2025 to provide clarity on the average occupancy rate for high occupancy. A reduction was made in the maintenance volume for special population pool beds, among other technical edits that received final approval from the commission during the September 2025 commission meeting. Changes are anticipated to be in effect during FY2026.
- **Heart, Lung, and Liver (HLL) Transplantation Services:** A SAC met and convened during FY2025 for changes to the HLL Transplantation Services review standards that would allow for a fourth (4th) liver location within the State of Michigan. The Commission too proposed action at the June 12, 2025, Commission meeting. Final action was disapproved during the September 18, 2025, Commission meeting and moved to seat a new SAC to review cost and quality implications of a fourth (4th) liver location in the State of Michigan. A new SAC will be convened during FY2026.
- **Cardiac Catheterization Services, Computed Tomography (CT) Scanner Services, Megavoltage Radiation Therapy (MRT) Services/Units, PET Scanner Services, Hospital Beds, OHS Services, Nursing Home and Hospital Long-Term-Care Unit (HLTCU) Beds, Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services, Psychiatric Beds and Services, UESWL Services, MRI Services, and Surgical Services:** A workgroup reviewed the standards during FY2025 to update the county designations for rural and metropolitan counties throughout the standards. The Commission took proposed action at their September 18, 2025, meeting. A public hearing and final action will be held during FY2026.
- **NICU and Special Newborn Nursing Services:** A workgroup convened during FY2025 to review the standards and will conclude during FY2026.
- **CT Scanner Services:** The review standards were reviewed by a SAC during FY2025 and will conclude during FY2026.
- **Cardiac Catheterization Services, Hospital Beds, MRT Services, OHS Services, PET Scanner Services, and Surgical Services:** A public comment period will be held during FY2026 to solicit feedback for potential changes to the referenced review standards. Workgroups and/or SACs will be determined for FY2026 as needed.

CON Required

In accordance with MCL 333.22209, a person or entity is required to obtain a CON, 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 CON Evaluation Section.
- Issuance of Proposed Decision by the PPOS 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.

FY2025 in Review

In FY2025, there were 357 Letters of Intent received resulting in 274 applications filed for CON review and approval. In addition, the Department received 69 amendments to previously approved applications. In total, the Department approved 242 proposed projects resulting in approximately \$1,285,644,070 of new capital expenditures into Michigan's health care system. The Department also surveyed 1,080 facilities and collected statistical data.

As required by the CON 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 FY2025, the CON Commission revised the review standards for Hospital Beds, Surgical Services, BMT Services, Cardiac Catheterization Services, MRI Services, and UESWL Services.

During FY2025, the CON Commission revised the review standards for Hospital Beds, Surgical Services, BMT Services, Cardiac Catheterization Services, MRI Services, and UESWL Services. In addition, the following CON standards were reviewed for modification: Psychiatric Beds and Services, NICU Beds, CT Scanner Services, and several CON Standards were reviewed to update the County designations for Rural and Metropolitan counties throughout the CON Standards.

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 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. 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 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 health care 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 FY2025.
<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 U.S. Food and Drug Administration for commercial use.
<i>SAC</i>	A SAC may be appointed by and report to the CON Commission. The SACs advise the Commission regarding creation of, or revisions to the standards. The Committees are composed of a 2/3 majority of experts in the subject matter and include representatives of organizations of health care providers 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 PPOS Administration.
<i>CASP Section</i>	The CASP Section within the PPOS 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>CON Evaluation Section</i>	<p>The CON Evaluation Section, also within the PPOS Administration, has operational responsibility for the program, including providing assistance to applicants prior to and throughout the CON process. The CON Evaluation Section is responsible for reviewing all Letters of Intent and applications as prescribed by the CON 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 CON Evaluation Section reviews requests for amendments to approved CONs as allowed by the CON Administrative Rules. Amendment requests involve a variety of circumstances, including changes in how an approved project is financed and authorization for cost overruns. The CON Evaluation 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 CON Evaluation Section also provides the Michigan Finance Authority (MFA) with information when health care 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 CON.

<i>Letter of Intent (LOI)</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 CON 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 CON 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 days 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 CON 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 PPOS Administration, in which the CON 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 LOIs 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.

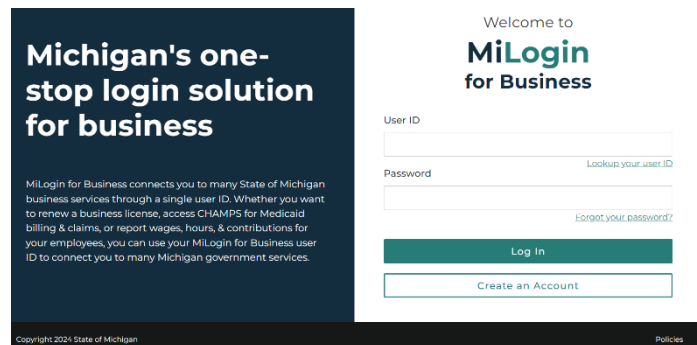
Table 1 provides an overview of the number of LOIs received and processed in accordance with the above-referenced Rule.

TABLE 1 Letters of Intent Received and Processed Within 15 Days FY2021 - FY2025				
	LOIs Received	Processed within 15 Days	Percent Processed within 15 Days	Waivers Processed*
FY2021	396	394	99%	37
FY2022	292	288	99%	53
FY2023	301	301	100%	65
FY2024	255	255	100%	49
FY2025	357	357	100%	52

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

In FY2025, LOIs were processed in a timely manner as required by CON 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 CON 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. In FY2025 100% of all LOIs and applicable applications are submitted online.



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TYPES OF CERTIFICATE OF NEED APPLICATION REVIEWS

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

Nonsubstantive

Nonsubstantive reviews involve projects that are subject to CON review but do not warrant a full review. The following describes 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 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 CON Evaluation Section within the Bureau up to 45 days from the date an application is deemed complete to issue a proposed decision. Reviewing these types of proposed projects on a nonsubstantive basis allows an applicant to receive a decision in a timely fashion while still being required to meet current CON requirements, including quality assurance standards.

Substantive Individual

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

Comparative

Comparative reviews involve situations where two or more applications are competing for a limited resource such as hospital or nursing home beds. A proposed decision for a comparative review project must be issued by the CON Evaluation Section within the Bureau no later than 120 days after the review cycle begins. The cycle begins when the determination is made that the project requires comparative review. According to the CON Administrative Rules, the Department has an 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 Feb, June, and Oct.

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 FY2025</i>	
1. Neonatal Intensive Care Unit	5. Nursing Home and HLTCU Beds
2. Hospital Beds	6. Nursing Home Beds for Special Population Groups
3. Psychiatric Beds	7. Psychiatric Beds for Special Population Groups
4. 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</i> <i>FY2021 - FY2025</i>					
	FY2021	FY2022	FY2023	FY2024	FY2025
<i>Nonsubstantive*</i>	191	146	113	120	188
<i>Substantive Individual</i>	84	78	79	65	80
<i>Comparative</i>	8	4	3	4	0
TOTALS	283	228	195	189	274

** Includes 1 swing bed application; does not include Emergency CONs.*

Table 3 provides a summary of applications received and processed in accordance with Rule 9201. The CON Administrative Rule requires the CON 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 FY2021 - FY2025					
	FY2021	FY2022	FY2023	FY2024	FY2025
Applications Received	283	228	195	193	274
Processed within 15 Days	282	227	195	192	273
Percent Processed within 15 Days	99%	99%	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 CON Evaluation Section to complete reviews by type.

TABLE 4 Average Number of Days in Review Cycle by Review Type FY2021- FY2025					
	FY2021	FY2022	FY2023	FY2024	FY2025
Nonsubstantive	37	40	36	34	35
Substantive Individual	105	118	110	98	107
Comparative	227	113	148	92	119

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 CON Evaluation Section within the Bureau attempts to issue emergency CON decisions to the Director for final review and approval within 10 days from receipt of request. In FY2025 the CON Evaluation Section within the Bureau issued the six (6) emergency CON decisions within an average of five (5) days.

TABLE 5 Emergency CON Decisions Issued FY2021 - FY2025					
	FY2021	FY2022	FY2023	FY2024	FY2025
Emergency CONs Issued	26	14	6*	4	6
Percent Issued within 10 Working Days	100%	100%	100%	100%	100%

**Emergency CON – application(s) submitted but withdrawn before a decision was to be issued.*

PROPOSED DECISIONS

Part 222 establishes a two-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 (CON Evaluation Section) to the applicant and the Department Director according to the timeframes established in the CON Administrative 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						
FY2021- FY2025						
	Nonsubstantive		Substantive Individual		Comparative	
	Issued	Issued on Time	Issued	Issued on Time	Issued	Issued on Time
<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%
<i>FY2025</i>	166	100%	72	100%	2	100%

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

TABLE 7					
Comparison of Proposed Decisions by Decision Type					
FY2021- FY2025					
	Approved	Approved w/ Conditions	Disapproved	Percent Disapproved	TOTAL
<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
<i>FY2025</i>	193	49	0	0%	242

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 CON 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

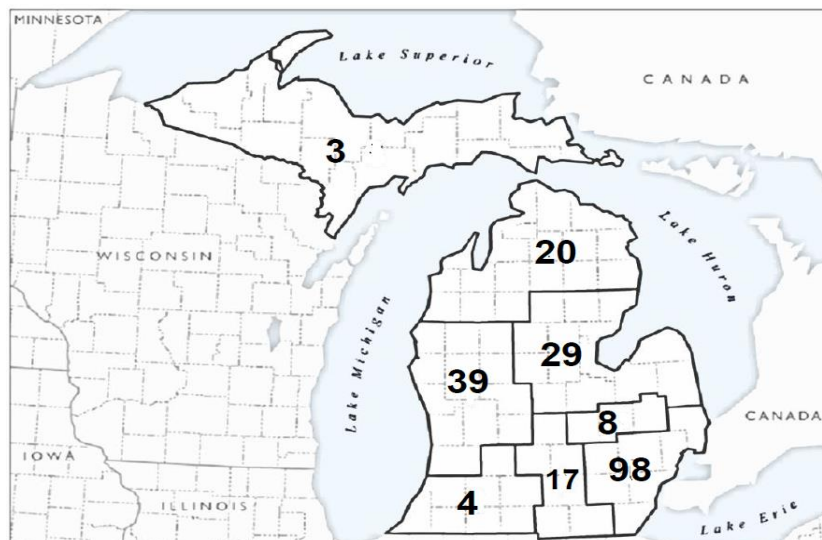
The Director issues a final decision on a CON application following either a proposed decision or the completion of a hearing, if requested, on a proposed decision. Pursuant to Section 22231(1) of the Public Health Code, the Director may issue a decision to approve an application, disapprove an application, 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 pertinent 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
FY2025 Final Decisions Issued
by Health Service Areas

TABLE 8 Final Decisions Issued FY2021 - FY2025	
FY2021	287
FY2022	261
FY2023	198
FY2024	190
FY2025	241



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 2024, the covered capital expenditure threshold was \$4,002,500 and as of January 1, 2025, the covered capital expenditure threshold was increased to \$4,175,000. The threshold is updated in January of every year.

TABLE 9					
Final Decisions Activity Category					
FY2021 - FY2025					
Approved	FY2021	FY2022	FY2023	FY2024	FY2025
Acquire, Begin, or Replace a Health Facility	43	50	29	22	37
Change in Bed Capacity	54	48	25	38	25
Covered Clinical Services	163	237	145	133	178
Covered Capital Expenditures	53	66	43	38	52
Disapproved					
Acquire, Begin, or Replace a Health Facility	23	1	0	0	0
Change in Bed Capacity	28	2	1	0	0
Covered Clinical Services	1	0	0	0	0
Covered Capital Expenditures	25	2	1	0	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				
FY2021 - FY2025				
	Approved	Approved with Conditions	Disapproved	Totals
Number of Final Decisions				
FY2021	168	90	29	287
FY2022	186	68	2	256
FY2023	162	35	1	198
FY2024	161	29	0	190
FY2025	191	50	0	241
Total Project Costs				
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
FY2025	\$855,354,324	\$430,289,746	\$0	\$1,285,644,070

Note: Final decisions include emergency CON applications.

In FY2025, 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				
FY2021 - FY2025				
	Number of Applications	Difference from Previous Year	Total Project Costs	Difference from Previous Year
Letters of Intent Processed				
<i>FY2021</i>	396	(6%)	\$2,443,097,718	31%
<i>FY2022</i>	300	(24%)	\$1,845,302,652	(24%)
<i>FY2023</i>	301	0.3%	\$3,531,890,321	91%
<i>FY2024</i>	254	(16%)	\$1,103,763,893	(69%)
<i>FY2025</i>	357	41%	\$1,501,860,486	36%
Applications Submitted				
<i>FY2021</i>	309	(9%)	\$1,703,931,501	(32%)
<i>FY2022</i>	255	(17%)	\$2,321,037,942	36%
<i>FY2023</i>	201	(21%)	\$1,159,033,442	(50%)
<i>FY2024</i>	192	(4%)	\$2,787,870,974	41%
<i>FY2025</i>	270	41%	\$1,265,526,939	(55%)
Final Decisions Issued				
<i>FY2021</i>	288	(9%)	\$1,944,965,809	(17%)
<i>FY2022</i>	287	(.03%)	\$2,517,447,509	29%
<i>FY2023</i>	198	(31%)	\$960,425,600	(62%)
<i>FY2024</i>	197	(0.5%)	\$2,797,161,789	91%
<i>FY2025</i>	241	22%	\$1,285,644,070	(54%)

Note: Applications submitted, and final decisions Issued include Emergency CONs and swing bed applications.

AMENDMENTS

The CON Administrative 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% 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 FY2021 - FY2025					
	FY2021	FY2022	FY2023	FY2024	FY2025
<i>Amendments Received</i>	57	74	66	66	69
<i>Amendment Decisions Issued</i>	57	61	80	60	70
<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 2025. Sixty-nine of the 241 CON approvals in FY2025 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 FY2025				
Covered Clinical Services/Beds	Existing Sites	Existing Units/Beds	New Sites	New Units/Beds
<i>Air Ambulances</i>	11	26	0	0
<i>Cardiac Catheterization Services</i>	58	239	1	3
<i>Primary PCI</i>	3	N/A	0	N/A
<i>Elective PCI</i>	16	N/A	0	N/A
<i>Open Heart Surgical Services</i>	*34	N/A	0	N/A
<i>Surgical Services</i>	287	1594	5	12
<i>CT Scanners Services</i>	267	403	16	8
<i>MRI Services</i>	354	267	4	0
<i>PET Services</i>	102	34	4	1
<i>Lithotripsy Services</i>	93	11	3	8
<i>MRT Services</i>	70	128	0	1
<i>Transplant Services</i>	6	N/A	0	N/A
<i>Hospitals</i>	161	25,061	0	15
<i>NICU Services</i>	21	654	0	0
<i>SCN Services</i>	14	111	0	0
<i>Extended Care Services Program (Swing Beds)</i>	44	413	0	5
<i>Nursing Homes/HLTCU</i>	443	45,438	1	32
<i>Psychiatric Hospitals/Units</i>	61	3,906	4	174
<i>Psychiatric Flex Beds</i>	4	96	0	0

Note: The source for the existing site and unit/bed information for Table 13 was the 2024 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 CY2024. New sites include LTAC Hospitals; mobile host sites for CT, Lithotripsy, MRI and PET services; & Psychiatric data includes special pool beds.

COMPLIANCE ACTIONS

Table 14 shows there were 191 projects requiring follow-up for FY2025 based on the Department's Monthly Follow-up/Monitoring Report as shown below.

TABLE 14					
Follow Up and Compliance Actions					
FY2021 - FY2025					
	FY2021	FY2022	FY2023	FY2024	FY2025
<i>Projects Requiring 1-year Follow-up</i>	314	261	264	203	191
<i>Approved CONs Expired</i>	95	62	204	73	51
<i>Compliance Orders Issued</i>	95	26	47	23	29

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 PET Scanner Services and OHS Services. All finalized compliance actions resulting from the statewide compliance reviews are reflected within the FY2025 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 Oct 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
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					
FY2021 – FY2025					
CON Fee	FY2021	FY2022	FY2023	FY2024	FY2025
\$ 0*	32	21	6	4	7
\$3,000	84	77	81	76	107
\$8,000	101	64	63	61	86
\$11,000	58	36	21	29	40
\$15,000	34	57	30	20	30
TOTAL	309	255	201	190	270

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					
FY2021 – FY2025					
CON Fee Category	FY2021	FY2022	FY2023	FY2024	FY2025
Complex Project	7	5	5	2	0
Expedited Review	26	12	39	28	30
LOI Waiver*	37	53	63	51	59
Amendment*	57	74	66	66	70
Annual Survey (Facilities)	1,094	1,091	1,087	1,099	1,080

*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 FY2021 – FY2025					
	FY2021	FY2022	FY2023	FY2024	FY2025
Program Cost	\$2,463,147	\$2,348,344	\$2,220,542	\$2,262,405	\$2,706,272
Fees/Funding	\$2,520,217	\$2,204,660	\$1,953,109	\$1,583,572	\$2,268,674
Fees % of Costs	100%+	94%	88%	70%	84%

Source: MDHHS Budget and Finance Administration.

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY2025, the CON Commission revised the review standards for Hospital Beds, Surgical Services, BMT Services, Cardiac Catheterization Services, MRI Services, and UESWL Services.

The revisions to the CON Review Standards for Hospital Beds received final approval by the CON Commission on September 19, 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 December 4, 2024. The final language changes include the following:

- 1. Section 2(1): Added a definition as follows:
 - (vi) HOSPITALS AS DEFINED UNDER MCL SECTION 333.21501(1)(i) AND HAVE BEEN APPROVED UNDER MCL SECTION 333.21551 TO DELICENSE 100% OF THEIR LICENSED BEDS.
- 2. Section 6: Added language for approval of new beds:
 - (3)(h) HOSPITALS DEFINED UNDER SECTION 2(1)(n)(vi) OF THIS STANDARD SHALL NOT APPLY FOR ADDITIONAL BEDS UNDER SECTION 6(3) UNTIL THE RECEIVING HOSPITAL HAS RELICENSED THE BEDS AS REQUIRED IN MCL SECTION 333.21511(7).
- 3. Section 9: Added project delivery requirements for new definition:
 - ((9) A HOSPITAL DEFINED UNDER MCL SECTION 333.21501(1)(i) SHALL ALSO MEET THE FOLLOWING REQUIREMENTS:
 - (a) THE HOSPITAL MUST NOTIFY THE DEPARTMENT OF THE DESIGNATION ACQUIRED AS REQUIRED IN MCL SECTION 333.21513(h).
 - (b) IF THE HOSPITAL CEASES TO MEET THE REQUIREMENTS OF MCL SECTION 333.21551 OR DECIDES TO PERMANENTLY DELICENSE BEDS AS PART OF MCL SECTION 333.21551. THEY MUST NOTIFY THE DEPARTMENT FOR BED INVENTORY PURPOSES.
 - (c) THE HOSPITAL WILL CONTINUE TO BE IN COMPLIANCE WITH THE REQUIREMENTS LISTED IN MCL SECTION 333.21551, AS APPLICABLE.
- 4. Other technical edits.

The revisions to the CON Review Standards for Surgical Services received final approval by the CON Commission on September 19, 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 December 4, 2024. The final language changes include the following:

- 1. Section 2(1): Modified/added definitions:
 - (a) "Ambulatory surgical center" or "ASC" means any distinct entity certified by Medicare as an ASC under the provisions of Title 42, Part 416 that operates exclusively for the purpose of providing surgical services IN A CON-APPROVED OPERATING ROOM to patients not requiring hospitalization, AND DEFINED AS A HEALTH FACILITY FOR PURPOSES OF PART 222 OF THE CODE.
 - (e) "CRITICAL ACCESS HOSPITAL" OR "CAH" MEANS A HOSPITAL DESIGNATED BY CMS PURSUANT TO 42 CFR 485.606.
 - (h) "DEDICATED DIALYSIS ACCESS CENTER" MEANS AN FSOF OR ASC USED EXCLUSIVELY FOR DIALYSIS ACCESS CASES.
 - (k) "DIALYSIS ACCESS" MEANS THE PHYSICAL CONDUIT BEING USED TO ACCESS THE PATIENT IN ORDER TO PROVIDE DIALYSIS.

- (l) “DIALYSIS ACCESS CASE” MEANS A SINGLE VISIT TO AN OPERATING ROOM DURING THE PERFORMANCE OF ONE OR MORE PROCEDURES FOR A PATIENT TO ESTABLISH OR MAINTAIN DIALYSIS ACCESS FOR THE PURPOSE OF PROVIDING HEMODIALYSIS OR PERITONEAL DIALYSIS FOR THE TREATMENT OF ADVANCED CHRONIC KIDNEY DISEASE, END STAGE RENAL DISEASE OR OTHER QUALIFYING CONDITION REQUIRING DIALYSIS. THESE PROCEDURES MAY INCLUDE VENOGRAPHY, FLUOROSCOPIC GUIDANCE OF CENTRAL VENOUS DIALYSIS ACCESS DEVICES, VASCULAR CATHETER PLACEMENT, REPAIR, REMOVAL, AND REPLACEMENT, VASCULAR CATHETER THROMBOLYSIS, REMOVAL OF OBSTRUCTIONS, FISTULAGRAMS, ANGIOPLASTY, ANGIOGRAM, STENT PLACEMENT, PERCUTANEOUS THROMBECTOMY, PERCUTANEOUS FISTULA CREATION, PERCUTANEOUS PERITONEAL DIALYSIS CATHETER PLACEMENT, REPAIR, REMOVAL, AND REPLACEMENT.
- (mq) “Freestanding surgical outpatient facility” or “FSOF” means a health facility licensed under Part 208 of the Code. AND PROVIDES OUTPATIENT SURGICAL SERVICES IN A CON-APPROVED OPERATING ROOM. It does not include a surgical outpatient facility owned and operated as a part of a licensed hospital site. A freestanding surgical outpatient facility is a health facility for purposes of Part 222 of the Code.
- (v) “MEDICARE DEPENDENT HOSPITAL” OR “MDH” MEANS A HOSPITAL DESIGNED BY CMS PURSUANT TO 42 CFR 412.108.
- (vaa) “Procedure room” means a room in a surgical facility constructed and equipped to perform surgical procedures and not located on a sterile corridor. PROCEDURES CONDUCTED IN PROCEDURE ROOMS ARE NOT CONSIDERED SURGICAL CASES.
- (cc) “SOLE COMMUNITY HOSPITAL” OR “SCH” MEANS A HOSPITAL DESIGNATED BY CMS PURSUANT TO 42 CFR 412.92
- (yee) “surgical case” means a single visit to an operating room during which one or more surgical procedures are performed. IN A CON-APPROVED OPERATING ROOM.
- 2. Section 3(2): Inventory of operating rooms used to perform surgical services; surgical cases, or hours of use; and evaluating compliance with minimum volume requirements:
 - (b) in an FSOF or ASC that is or will be used exclusively for endoscopy, or cystoscopy, or DIALYSIS ACCESS cases all rooms in which endoscopy, or cystoscopy, OR DIALYSIS ACCESS cases are or will be performed.
 - (c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy, or cystoscopy OR DIALYSIS ACCESS cases. All operating rooms in which surgery is or will be performed, excluding any operating rooms used exclusively for endoscopy, or cystoscopy, OR DIALYSIS ACCESS.
- 3. Section 3(3): Modifications:
 - (b) In an FSOF or ASC that is or will be used exclusively for endoscopy, or cystoscopy, OR DIALYSIS ACCESS cases, all endoscopy, or cystoscopy, OR DIALYSIS ACCESS cases, or hours of use, performed in the operating rooms identified in subsection (2)(b).
 - (c) In an FSOF or ASC that is or will be used exclusively for endoscopy, or cystoscopy, OR DIALYSIS ACCESS cases, all surgical cases, or hours of use, performed in the operating rooms identified in subsection (2)(c). Cases, or hours of use, performed in any operating room used exclusively for endoscopy, or cystoscopy, OR DIALYSIS ACCESS cases, shall be excluded.
- 4. Section 4: Requirements to initiate a surgical service:

- (2) Subsection (1) shall not apply if the proposed project involves the initiation of a surgical service with 1 or 2 operating rooms at a licensed hospital THAT IS A CRITICAL ACCESS HOSPITAL, SOLE COMMUNITY HOSPITAL, OR MEDICARE DEPENDENT HOSPITAL, OR A LICENSED HOSPITAL site located in a rural or micropolitan statistical area county that does not offer surgical services as of the date an application is submitted to the Department.
- (4) AN APPLICANT PROPOSING TO INITIATE A DEDICATED DIALYSIS ACCESS CENTER SHALL ONLY USE DIALYSIS ACCESS CASES IN ACCORDANCE WITH SECTION 11 (1)(e).
- 5. Section 5: Modifications:
 - To replace a surgical service or one or more operating rooms, means:
 - (i) ~~the~~ THE development of new space (whether through new construction, purchase, lease or similar arrangement) to house one or more operating rooms operated by an applicant at the same site as the operating room(s) to be replaced;
 - (ii) ~~This also includes designating~~ DESIGNATING an OR as a dedicated endoscopy or cystoscopy OR.;
 - (iii) ~~The term also includes relocating~~ RELOCATING an existing surgical facility WITH or one or more operating rooms to a new geographic location of ~~an~~ THAT existing surgical facility; or
 - (iv) RELOCATING one or more operating rooms OF AN EXISTING SURGICAL FACILITY to a different GEOGRAPHIC location currently offering surgical services AS ANOTHER EXISTING SURGICAL FACILITY.
 - (v) The term does not include the renovation of an existing surgical service or one or more operating rooms.
 - (vi) An applicant requesting to replace an existing surgical service shall demonstrate each of the following, as applicable to the proposed project.
- 6. Section 5(1): Modifications for clarification:
 - (1) An applicant proposing to replace shall demonstrate:
 - (a) All existing operating rooms in the existing surgical facility have performed an average of at least THE FOLLOWING, UTILIZING THE MOST RECENT 12 MONTHS OF DATA WHICH IS VERIFIABLE BY THE DEPARTMENT:
 - (i) 1,042 surgical cases ~~per year per operating room, for which verifiable data is available to the Department,~~ or
 - (ii) 1,125 hours of use in a facility that performs only outpatient surgery, ~~per year per operating room, for which verifiable data is available to the Department,~~ or
 - (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use. as billed by the facility. ~~per year per operating room for which verifiable data is available to the Department~~ and calculated as follows:
 - (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of INPATIENT hours of use (~~inpatient surgical volume~~) and OUTPATIENT surgical cases, (~~outpatient surgical volume~~) as billed by the facility, ~~per year per operating room for which verifiable data is available to the Department and calculated as follows:~~
 - (b) ~~All operating rooms, existing and replaced, are projected to perform an average of at least:~~
 - (i) ~~1,042 surgical cases per year per operating room in the second twelve months of operation, and annually thereafter, or~~

- ~~(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in the second twelve months of operation, and annually thereafter, or~~
- ~~(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:~~
- ~~(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus 253 the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours 254 would equate to $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$ OR.), or~~
- ~~(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:~~
- ~~(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$ OR.)~~
- 7. Section 5(2): Modifications for clarification:
 - (2) An applicant proposing to replace one or more operating rooms at a licensed hospital and is located 264 in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of 265 not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent federal decennial census OR THE APPLICANT IS A CRITICAL ACCESS HOSPITAL, SOLE COMMUNITY HOSPITAL, OR MEDICARE DEPENDENT HOSPITAL shall demonstrate each of the following:
 - (a) The applicant has ~~three, four, or five ORs~~ LESS THAN SIX ORS at the licensed hospital.
 - (b) All existing operating rooms have performed an average of at least ONE OF THE FOLLOWING UTILIZING THE MOST RECENT 12 MONTHS OF DATA VERIFIABLE BY THE DEPARTMENT:
 - (i) ~~839 surgical cases per year per operating room, for which verifiable data is available to the Department, or~~
 - (ii) ~~1,200 906 hours of use per year per operating room. for which verifiable data is available to the Department.~~
 - (c) All operating rooms, existing and replaced, are projected to perform an average of at least:
 - (i) ~~839 surgical cases per year per operating room in the second twelve months of operation, and annually thereafter, or~~
 - (ii) ~~1,200 906 hours of use per year per operating room in the second twelve months of operation, and annually thereafter.~~
- 8. Section 5(3): Updated to include access for rural hospitals:
 - (3) Subsections (1) and (2) shall not apply if the proposed project involves replacing one or more operating rooms at the same licensed hospital site IS A CRITICAL ACCESS HOSPITAL, SOLE COMMUNITY HOSPITAL, OR MEDICARE DEPENDENT HOSPITAL, OR if the surgical facility is located in a rural or micropolitan statistical area county and has one or two operating rooms.
- 9. Section 5(6): Modifications for clarification:

- (6) An applicant proposing to relocate an existing surgical service, or one or more operating rooms shall demonstrate each of the following, as applicable:
- (b) All existing operating rooms in the surgical facility from which one or more ORs are proposed to be relocated have performed an average of at least ONE OF THE FOLLOWING UTILIZING THE MOST RECENT 12 MONTHS OF DATA VERIFIABLE BY THE DEPARTMENT:
 - (i) 1,042 surgical cases per year per operating room, ~~for which verifiable data is available to the Department,~~ or
 - (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room ~~for which verifiable data is available to the Department,~~ or,
 - (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use, as billed by the facility, ~~per year per operating room for which verifiable data is available to the Department~~ and calculated as follows:
 - (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of INPATIENT hours of use ~~(inpatient surgical volume)~~ and OUTPATIENT surgical cases, ~~(outpatient surgical volume)~~ as billed by the facility, ~~per year per operating room for which verifiable data is available to the Department~~ and calculated as follows:
 - (v) AN EXISTING SURGICAL FACILITY APPLICANT THAT IS PROPOSING TO RELOCATE ONE OR MORE OPERATING ROOMS TO ANOTHER EXISTING SURGICAL FACILITY IS NOT REQUIRED TO MEET SUBSECTIONS 5(6)(B)(I)-(IV).
 - (vi) THE RELOCATED OPERATING ROOMS SHALL BE LICENSED TO THE RECEIVING EXISTING SURGICAL FACILITY AND THE APPLICANT SHALL AGREE TO DECREASE THEIR TOTAL NUMBER OF OPERATING ROOMS, AS APPLICABLE.
- (c) All operating rooms, existing and relocated, AT THE RECEIVING EXISTING SURGICAL FACILITY, are projected to perform an average of at least THE FOLLOWING IN THE SECOND TWELVE MONTHS OF OPERATIONS:
 - (i) 1,042 surgical cases ~~per year per operating room in the second twelve months of operation or~~
 - (ii) 1,125 hours of use in a facility that performs only outpatient surgery ~~per year per operating room, in the second twelve months of operation,~~ and annually thereafter, or
 - (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use, as billed by the facility, per year per operating room, in the second twelve months of operation, and annually thereafter and calculated as follows:
 - (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of INPATIENT hours of use ~~(inpatient surgical volume)~~ and OUTPATIENT surgical cases, ~~(outpatient surgical volume)~~ as billed by the facility, ~~per year per operating room, in the second twelve months of operation,~~ and annually thereafter and calculated as follows:
 - (d) THE EXISTING SURGICAL SERVICE FROM WHICH THE OPERATING ROOMS ARE BEING RELOCATED, AND THE EXISTING SURGICAL SERVICE RECEIVING THE OPERATING ROOMS, SHALL NOT REQUIRE ANY OWNERSHIP RELATIONSHIP.
- 10. Section 5(7): Updated to include access for rural hospitals:
 - (7) Subsection (6) shall not apply if the proposed project involves relocating one or two operating rooms within a 20-mile radius if the surgical facility IS A

CRITICAL ACCESS HOSPITAL, SOLE COMMUNITY HOSPITAL, OR MEDICARE DEPENDENT HOSPITAL, OR is located in a rural or micropolitan statistical area county.

- 11. Section 5(8): Updated to include access for rural hospitals and modifications for clarification:
 - (8) An applicant proposing to relocate AN EXISTING SURGICAL SERVICE OR one or more operating rooms from one licensed hospital site to another licensed hospital site and is located in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent federal decennial census OR THE APPLICANT IS A CRITICAL ACCESS HOSPITAL, SOLE COMMUNITY HOSPITAL, OR MEDICARE DEPENDENT HOSPITAL, shall demonstrate each of the following:
 - (a) The applicant has ~~three, four, or five ORs~~ LESS THAN SIX ORS at the licensed hospital FROM WHICH ONE OR MORE OPERATING ROOMS ARE PROPOSED TO BE RELOCATED.
 - (b) All existing operating rooms have performed an average of at least ONE OF THE FOLLOWING UTILIZING THE MOST RECENT 12 MONTHS OF DATA THAT IS VERIFIABLE BY THE DEPARTMENT:
 - (i) 839 surgical cases ~~per year~~ per operating room, ~~for which verifiable data is available to the Department,~~ or
 - (ii) ~~4,200~~ 906 hours of use ~~per year~~ per operating room, ~~for which verifiable data is available to the Department.~~
 - (iii) AN EXISTING LICENSED HOSPITAL THAT IS PROPOSING TO RELOCATE ONE OR MORE OPERATING ROOMS TO ANOTHER EXISTING LICENSED HOSPITAL IS NOT REQUIRED TO MEET SUBSECTIONS 5(8)(b)(i)-(ii),
 - (iv) THE RELOCATED OPERATING ROOMS SHALL BE LICENSED TO THE RECEIVING EXISTING LICENSED HOSPITAL AND THE APPLICANT SHALL AGREE TO DECREASE THEIR TOTAL NUMBER OF OPERATING ROOMS, AS APPLICABLE.
 - (c) All operating rooms, existing and relocated, AT THE RECEIVING LICENSED HOSPITAL are projected to perform an average of at least THE FOLLOWING IN THE SECOND TWELVE MONTHS OF OPERATIONS:
 - (i) 839 surgical cases ~~per year~~ per operating room ~~in the second twelve months of operation~~ or
 - (ii) ~~4,200~~ 906 hours of use per year per operating room. in the second twelve months of operation,
 - (d) THE EXISTING LICENSED HOSPITAL FROM WHICH THE OPERATING ROOMS ARE BEING RELOCATED, AND THE EXISTING LICENSED HOSPITAL RECEIVING THE OPERATING ROOMS, SHALL NOT REQUIRE ANY OWNERSHIP RELATIONSHIP.
- 12. Section 5(9): Updated to accommodate prior changes:
 - (9) An applicant shall demonstrate that it meets the requirements of Section 11(2) for the number of 385 surgical cases, or hours of use, projected under subsections ~~(1), (2), (6),~~ and (8).
- 13. Section 6: Modifications for clarification:
 - (1) An applicant shall demonstrate the following:
 - (a) All existing operating rooms in the existing surgical facility have performed an average of at least ONE OF THE FOLLOWING UTILIZING THE MOST RECENT 12 MONTHS OF DATA THAT IS VERIFIABLE BY THE DEPARTMENT:

- (i) 1,216 surgical cases ~~per year per operating room, for which verifiable data is available to the Department,~~ or
- (ii) 1,313 hours of use in a facility that performs only outpatient surgery ~~per year per operating room, for which verifiable data is available to the Department,~~ or
- (iii) a licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use, as billed by the facility per year, per operating room, ~~for which verifiable data is available to the Department~~ and calculated as follows:
- (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of INPATIENT hours of use (~~inpatient surgical volume~~) and OUTPATIENT surgical cases, (~~outpatient surgical volume~~) as billed by the facility, ~~per year per operating room for which verifiable data is available to the Department~~ and calculated as follows:
- (v) ALL EXPANSION VOLUME UNDER THIS SUBSECTION MUST BE BASED ON EXISTING SURGICAL CASES AND/OR HOURS PERFORMED IN EXISTING OPERATING ROOMS, NOT PROPOSED, PROJECTED CASES BASED ON A TREND OF INCREASED VOLUME AT A FACILITY.
- (b) All proposed operating rooms, INCLUDING EXISTING OPERATING ROOMS, are projected to perform an average of at least THE FOLLOWING IN THE SECOND TWELVE MONTHS OF OPERATIONS:
 - (i) 1,042 surgical cases ~~per year per operating room in the second twelve months of operation,~~ or
 - (ii) 1,125 hours of use in a facility that performs only outpatient surgery ~~per year per operating room, in the second twelve months of operation,~~ or
 - (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility ~~per year per operating room in the second twelve months of operation,~~ and calculated as follows:
 - (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of INPATIENT hours of use (~~inpatient surgical volume~~) and OUTPATIENT surgical cases, (~~outpatient surgical volume~~) as billed by the facility, ~~per year per operating room in the second twelve months of operation,~~ and calculated as follows:
 - (c) AN APPLICANT WHOSE EXISTING OPERATING ROOMS IN THE EXISTING SURGICAL FACILITY HAVE PERFORMED AN AVERAGE OF AT LEAST 1650 SURGICAL CASES OR 1750 HOURS OF USE PER OPERATING ROOM IN THE PREVIOUS 12 MONTHS FOR WHICH VERIFIABLE DATA IS AVAILABLE SHALL QUALIFY TO ADD ONE (1) ADDITIONAL OPERATING ROOM AND SHALL NOT BE SUBJECT TO SUBSECTIONS (a) OR (b) ABOVE.
 - (2) An applicant proposing to add one or more operating rooms at a licensed hospital ~~and is located in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent federal decennial census,~~ OR THE APPLICANT IS A CRITICAL ACCESS HOSPITAL, SOLE COMMUNITY HOSPITAL, OR MEDICARE DEPENDENT HOSPITAL, shall demonstrate each of the following:
 - (a) The applicant has ~~two, three, or four ORs~~ LESS THAN SIX ORS at the licensed hospital.
 - (b) All existing operating rooms have performed an average of at least ONE OF THE FOLLOWING 450 UTILIZING THE MOST RECENT 12 MONTHS OF DATA VERIFIABLE BY THE DEPARTMENT:

- (i) 979 surgical cases ~~per year~~ per operating room, ~~for which verifiable data is available to the Department,~~ or
- (ii) ~~4,400~~ 1,057 hours of use ~~per year~~ per operating room. ~~for which verifiable data is available to the Department.~~
- (c) All proposed operating rooms, INCLUDING EXISTING OPERATING ROOMS, are projected to 456 perform an average of at least THE FOLLOWING IN THE SECOND TWELVE MONTHS OF OPERATIONS:
 - (i) 839 surgical cases per year per operating room, in the second twelve months of operation, or
 - (ii) ~~4,200~~ 906 hours of use per year per operating room in the second twelve months of operation.
- (5) FOR AN APPLICANT PROPOSING TO ADD ONE OR MORE OPERATING ROOMS TO A DEDICATED DIALYSIS ACCESS CENTER THAT APPLICANT SHALL ONLY USE DIALYSIS ACCESS 470 CASES SUBJECT TO SECTION 11 (1)(e).
- 14. Section 9: Requirements for Medicaid Participation:
 - Sec 9. An applicant shall provide Verification of THE FACILITY'S Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved. AN INDIVIDUAL PHYSICIAN'S NATIONAL PROVIDER IDENTIFIER (NPI) NUMBER SHALL NOT SUFFICE AS PROOF OF A FACILITY'S MEDICAID PARTICIPATION.
- 15. Section 10: Requirements for Medicaid Participation:
 - (4) Compliance with the following monitoring and reporting requirements:
 - (b) Existing operating rooms, located in a rural or micropolitan county, or within a city, village, or township with a population of not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent Federal decennial census OR THE FACILITY IS A CRITICAL ACCESS HOSPITAL, SOLE COMMUNITY HOSPITAL, OR MEDICARE DEPENDENT HOSPITAL in a surgical service that has ~~three, four, or five~~ OR'S LESS THAN 6 OR's shall perform an average of at least:
 - (ii) ~~4,200~~ 906 hours of use ~~per year~~ per operating room verifiable by the department.
 - (c) The applicant shall participate in a data collection System established and administered by the Department. The data may include, but is not limited to, hours of use of operating rooms, annual budget and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to patients from all payer sources. An applicant shall provide the required data on a separate basis for each licensed or certified site, in a format established by the department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records. MINIMUM VOLUME REQUIREMENTS SHALL NOT APPLY IF THE LICENSED HOSPITAL HAS LESS THAN 3 ORS AND IS A CRITICAL ACCESS HOSPITAL, SOLE COMMUNITY HOSPITAL, OR MEDICARE DEPENDENT HOSPITAL, OR IS LOCATED IN A RURAL OR MICROPOLITAN COUNTY.
 - (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).

- 16. Section 11: Clarification to reasonable projections:
 - Sec 11. (1) An applicant required to project volumes of service shall specify how the volume projections were developed and shall include only those surgical cases performed in an OR.
 - (a) The applicant shall include a description of the data source(s) used as well as an assessment of the accuracy of these data used to make the projections. THE PROJECTIONS MUST USE MOST RECENT 12 MONTHS OF DATA VERIFIABLE BY THE DEPARTMENT. IF THE APPLICANT IS NOT UTILIZING ANNUAL SURVEY DATA, THEN THEY MUST PROVIDE A DETAILED LIST OF SURGICAL CASES FOR EACH COMMITTING FACILITY. Based on this documentation, the Department shall determine if the projections are reasonable.
 - (b) The Department shall subtract any previous commitment, pursuant to subsection 2(d).
 - (c) AN APPLICANT COMMITTING CASES FROM A HOSPITAL TO AN FSO OR ASC APPLICATION, SHALL NOT UTILIZE INPATIENT CASE COMMITMENTS (OR HOURS OF USE) IN THE CON APPLICATION FOR PROJECTIONS.
 - (d) THE DEPARTMENT SHALL ACCEPT PROJECTIONS THAT INCLUDE APPLYING A SPECIFIED PERCENTAGE OF PROJECTED FUTURE GROWTH IF THAT PERCENTAGE IS LESS THAN OR EQUAL TO THE AVERAGE ANNUAL PERCENTAGE OF GROWTH SEEN AT THE APPLICANT'S FACILITY OVER THE PREVIOUS 5 YEARS.
 - (e) IF AN APPLICANT IS APPLYING FOR A DEDICATED DIALYSIS ACCESS CENTER, THAT APPLICANT SHALL ONLY USE DIALYSIS ACCESS CASES FOR PROJECTED VOLUME. FOR THE PURPOSES TO INITIATE OR EXPAND SURGICAL SERVICES FOR A DEDICATED DIALYSIS ACCESS CENTER, AN APPLICANT MAY USE DIALYSIS ACCESS CASES THAT WERE PERFORMED OUTSIDE OF AN OR AS LONG AS THE DIALYSIS ACCESS CASES WERE PERFORMED IN A FACILITY CERTIFIED BY THE JOINT COMMISSION FOR DIALYSIS ACCESS CASES.
 - (f) AN APPLICANT FACILITY THAT IS NOT OR WILL NOT BE USED EXCLUSIVELY FOR DIALYSIS ACCESS CASES SHALL NOT UTILIZE ANY DIALYSIS ACCESS CASES PERFORMED AT A DEDICATED DIALYSIS ACCESS CENTER IN THE CON APPLICATION FOR PROJECTIONS.
- 17. Section 12: Technical edits:
 - Sec. 12. Proposed projects reviewed under these standards shall not be subject to comparative review. These CON review standards ~~supersede~~ SUPERSEDE and replace the CON Review Standards for Surgical Facilities approved by the CON Commission on ~~September 25, 2014~~ September 21, 2017 and effective on ~~December 22, 2014~~ November 17, 2017.

The revisions to the CON Review Standards for Bone Marrow Transplantation (BMT) Services received final approval by the CON Commission on September 19, 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 December 4, 2024. The final language changes include the following:

- 1. The Title of the Standards:
 - MICHIGAN DEPARTMENT OF ~~COMMUNITY~~ HEALTH AND HUMAN SERVICES
- 2. Section 2: Definitions:

- (i) "Department" means the Michigan Department of ~~Community~~ Health AND HUMAN SERVICES (MDGHHS)
- 3. Section 7: Project Delivery Requirements terms of approval for all applicants:
 - (j) 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 Cardiac Catheterization Services received final approval from the CON Commission on June 23, 2025 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 August 27, 2025. The final language changes include the following:

- 1. Section 2 definitions were updated, modified, and added as follows:
 - (d) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, performed on a patient during a single session in a laboratory. Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X rays and an electronic image intensifier are used as aides in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart. This term does not include "float catheters" that are performed at the bedside or in settings outside the laboratory. ~~or the implantation of cardiac permanent pacemakers and implantable cardioverter defibrillators (ICD) devices~~ THE TERM DOES NOT INCLUDE CIED PROCEDURES that are performed in an interventional radiology laboratory or operating room in a licensed hospital, THAT ~~and~~ has CON APPROVAL FOR diagnostic cardiac catheterization OR IN AN FSOF THAT HAS CON APPROVAL FOR DIAGNOSTIC CARDIAC CATHETERIZATION AND CIED PROCEDURES.
 - (g) "Cardiac implantable electronic device (CIED) procedure" means ANY PROCEDURE INVOLVING THE IMPLANTATION, REVISION, RELOCATION, OR EXTRACTION OF A PACEMAKER OR ICD DEVICE, EXCEPT LEADLESS PACEMAKERS. THE TERM INCLUDES ALL GENERATOR CHANGES. THE TERM INCLUDES THE INSERTION, REVISION, RELOCATION, OR EXTRACTION OF ALL LEADS, EXCEPT FOR PROCEDURES INVOLVING LEADS GREATER THAN 12 MONTHS OLD. A FACILITY THAT PROVIDES CIED PROCEDURES MAY ALSO PERFORM RIGHT-SIDED CARDIAC ABLATION PROCEDURES EXCEPT VENTRICULAR TACHYCARDIA ABLATIONS. ~~implantation of transvenous single and dual chamber pacemaker, transvenous single and dual chamber implantable cardioverter defibrillators (ICDS), and all generator changes.~~
 - (k) "CORONARY ATHERECTOMY" MEANS ORBITAL OR ROTATIONAL ATHERECTOMY FOR CALCIUM MODIFICATION.
 - (m) "Diagnostic cardiac catheterization procedure" includes right heart catheterization, left heart catheterization, coronary angiography, coronary artery bypass graft angiography, intracoronary administration of drugs, fractional flow reserve (FFR), intra-coronary imaging such as intravascular

- ultrasound (IVUS), optical coherence tomography (OCT), or near-infrared spectroscopy (NIRS) when performed without a therapeutic procedure, ~~cardiac biopsy~~, intra-cardiac echocardiography, and DIAGNOSTIC electrophysiology study.
- ~~(mn)~~ "Diagnostic cardiac catheterization service" means providing diagnostic cardiac catheterization procedures on an organized, regular basis in a laboratory to diagnose anatomical and/or physiological problems in the heart.
 - (i) A hospital that ~~provides~~ HAS CON APPROVAL FOR diagnostic cardiac catheterization services MAY ALSO PERFORM CIED PROCEDURES.
 - (ii) A FSOE THAT HAS CON APPROVAL FOR DIAGNOSTIC CARDIAC CATHETERIZATION AND CIED PROCEDURES may also perform ~~permanent pacemaker and ICD implantation (therapeutic procedures)~~ CIED PROCEDURES.
 - (iii) A FACILITY THAT HAS CON APPROVAL FOR DIAGNOSTIC CARDIAC CATHETERIZATION SERVICES MAY ALSO PERFORM MECHANICAL CIRCULATORY SUPPORT, (E.G., IABP, IMPELLA, ETC) PERICARDIOCENTESIS, TRANSVENOUS PACEMAKER, ON AN URGENT OR EMERGENT BASIS TO STABILIZE A PATIENT.
 - ~~(sf)~~ "Elective PCI services without on-site open heart surgery (OHS)" means performing PCI on an organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary PCI service but not having OHS on-site and adhering to patient selection as outlined in the SCAI EXPERT CONSENSUS STATEMENT ON PERCUTANEOUS CORONARY INTERVENTION WITHOUT ON-SITE SURGICAL BACKUP (GRINES CL ET AL, JSCAI GRINES, JOURNAL OF THE SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY & INTERVENTIONS, VOLUME 2, ISSUE 2, 2023) SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site Surgical Backup and published in Circulation 2014, 129:2610-2626 and its update or further guideline changes. A hospital that provides elective PCI without on-site OHS may also perform LEADLESS PACEMAKER PROCEDURES, CORONARY ATHERECTOMY, AND CARDIAC ABLATION PROCEDURES EXCEPT VENTRICULAR TACHYCARDIA ABLATIONS ~~AND CORONARY ATHERECTOMY~~. A FACILITY THAT PROVIDES ELECTIVE PCI WITHOUT ON-SITE OHS MAY ALSO PERFORM MYOCARDIAL BIOPSY ONLY ON PATIENTS WHO HAVE UNDERGONE A PREVIOUS HEART TRANSPLANT. ~~right-sided cardiac ablation procedures including right atrial flutter, AV reentry, AV node reentry, right atrial tachycardia, and AV node ablation.~~
 - (v) "ICD" MEANS AN IMPLANTABLE CARDIOVERTER DEFIBRILLATOR OR A SUBCUTANEOUS IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR.
 - ~~(bbz)~~ "Primary PCI service without on-site OHS" means performing primary PCI on an emergent basis in a hospital having a diagnostic cardiac catheterization service. A hospital that provides primary PCI without on-site OHS may also perform LEADLESS PACEMAKER PROCEDURES AND CARDIAC ABLATION PROCEDURES EXCEPT VENTRICULAR TACHYCARDIA ABLATIONS. ~~right-sided cardiac ablation procedures including right atrial flutter, AV reentry, AV node reentry, right atrial tachycardia, and AV node ablation.~~

- ~~(ffdd)~~ “Therapeutic cardiac catheterization session” may include: CARDIOMEMS, PCI (elective, emergent), pericardiocentesis, CARDIAC ABLATION, STRUCTURAL HEART PROCEDURES, PACEMAKER, ICD, LEAD, GENERATOR PROCEDURES, OR MYOCARDIAL BIOPSY. ~~permanent pacemaker implantation, ICD implantation (endovascular or subcutaneous), pacemaker or ICD generator change, pacemaker or ICD lead revision, cardiac ablation, and/or structural heart procedure,~~ This also includes implantation of a circulatory support device such as IABP, Impella, ECMO or TandemHeart where this is the only therapeutic procedure. when PCI is performed in more than one coronary artery during the same setting, this is counted as one session.
- 2. Section 4(1): Modified/added language to allow certain cardiac catheterization procedures to be performed in hospitals without on-site open-heart surgery:
 - (f)(vii) Written protocols, signed by the applicant hospital and the OHS hospital, for the immediate transfer within 60 minutes travel time from the cardiac catheterization laboratory to evaluation on site in the OHS hospital, of patients requiring surgical evaluation and/or intervention 365 days a year. If the applicant hospital CAN DEMONSTRATE THAT THERE IS NO OHS SERVICE WITHIN 60 RADIUS MILES OR 60 MINUTES TRAVEL TIME FROM THE PROPOSED SITE ~~meets the requirements of subsection (1)(m)(iii),~~ then the OHS hospital can be more than 60 minutes travel time from the proposed site. The protocols shall be reviewed and tested on a quarterly basis.
 - ~~(mn)(iii) If the applicant hospital was not approved as a primary PCI service prior to September 14, 2015, then, in addition, the applicant hospital shall demonstrate that there is no PCI or OHS service within 60 radius miles or 60 minutes travel time from the proposed site.~~
 - ~~(no)~~ If the applicant hospital is currently providing OHS services and therapeutic cardiac catheterization services and is proposing to discontinue OHS services and therapeutic cardiac catheterization services, then the applicant hospital shall apply to initiate primary ~~or~~ AND elective PCI services without on-site OHS using this section. The applicant hospital shall demonstrate all of the requirements in this section ~~except for subsection (13)~~ and is subject to all requirements in Section 10.
- 3. Modified/added language to consider cardiac catheterization services in rural areas, including initiation requirements for elective PCI:
 - Section 4(1): (l)(ii) If the applicant hospital is applying for an elective PCI service without on-site OHS, the applicant hospital shall project a minimum of 200 PCI procedures per year IF LOCATED IN A METROPOLITAN STATISTICAL AREA COUNTY, OR 100 PCI PROCEDURES PER YEAR IF LOCATED WITHIN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.
 - (m) AN APPLICANT HOSPITAL SHALL AGREE THAT, IF APPROVED, IT WILL NOT BEGIN PERFORMING LEFT-SIDED ABLATIONS UNTIL IT HAS PERFORMED AT LEAST 10 RIGHT-SIDED ABLATIONS IN A 12 MONTH PERIOD.
 - Section 12(3) An applicant proposing to initiate an elective PCI service without on-site OHS services, whether in a hospital or FSO, shall demonstrate and certify that the proposed service shall treat 200 or more patients, OR 100 OR MORE PATIENTS IF A HOSPITAL IS LOCATED IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY, with PCI annually using data

from the most recent 12-month period preceding the date the application was submitted to the Department as follows and applicable:

- (a) All primary PCIs performed at the applicant hospital.
 - (b) All ~~in~~REGISTERED patients transferred from the applicant hospital to another hospital for PCI.
 - (c) 90% of patients who received diagnostic cardiac catheterizations at the applicant facility and received an elective PCI at another cardiac catheterization service within 30 days, FOR AN APPLICANT IN A METROPOLITAN STATISTICAL AREA COUNTY OR 60 DAYS FOR AN APPLICANT IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY, of the diagnostic catheterization (based on physician commitments).
- 4. Section 8: Modifications to allow for Hybrid/OR Cardiac Cath labs in facilities other than those with open-heart surgery onsite:
- Sec. 8. A hybrid OR/CCL means an operating room located on a sterile corridor and equipped with an angiography system PERFORMING minimally invasive procedures of the heart and blood vessels with full anesthesia capabilities. An applicant hospital OR FSOF proposing to add one or more hybrid OR/CCLs at an existing OR PROPOSED cardiac catheterization service shall demonstrate each of the following:
 - (1) The applicant hospital operates, ~~an OHS service which is in full compliance with the current CON Review Standards for OHS Services.~~ OR PROPOSES TO OPERATE, A DIAGNOSTIC CARDIAC CATHETERIZATION SERVICE AND A PRIMARY OR ELECTIVE PCI SERVICE WITHOUT ON-SITE OHS; OR A THERAPEUTIC SERVICE; AND IS IN COMPLIANCE WITH SECTIONS 3, 4, AND 10 OF THESE STANDARDS AS APPLICABLE.
 - (2) The applicant FSOF operates, OR PROPOSES TO OPERATE, a DIAGNOSTIC ~~therapeutic~~ cardiac catheterization SERVICE AND ELECTIVE PCI SERVICE AND ~~program which is in full compliance with Sections 3(2)4 and 10(4) of these standards, AS APPLICABLE.~~
 - (3) THE APPLICANT AGREES TO PERFORM ONLY THOSE CARDIAC CATHETERIZATION PROCEDURES IN THE HYBRID OR/CCL THAT ARE AUTHORIZED UNDER THE APPLICABLE DEFINITONS OF SERVICE LEVELS APPROVED AT THE FACILITY.
 - (4) THE APPLICANT SHALL SUBMIT A DOCUMENT EXPLAINING THE JUSTIFICATION OF ADDING THE HYBRID OR/CCL AND OUTLINING THE OPERATIONAL NARRATIVE FOR UTILIZING THE HYBRID OR/CCL AND WHAT TYPES OF PROCEDURES WILL BE PERFORMED.
 - (35) If the hybrid OR/CCL(s) represents an increase in the number of cardiac catheterization laboratories at the facility, the applicant ~~hospital~~ FACILITY is in compliance with SECTION 4 OR Section 6 of these standards.
 - (46) If the hybrid OR/CCL(s) represents conversion of an existing cardiac catheterization laboratory(s), the applicant ~~hospital~~ FACILITY is in compliance with the provisions of Section 5, if applicable.
 - (57) The applicant ~~hospital~~ FACILITY meets the applicable requirements of the CON Review Standards for Surgical Services.
 - (79) For each hybrid OR/CCL APPROVED AND OPERATIONAL, a facility shall have 0.5 excluded from its inventory of cardiac catheterization laboratories for the purposes of computing the procedure equivalents per room, FOR REPLACEMENT UNDER SECTION 5, FOR EXPANSION UNDER SECTION 6,

FOR ACQUISITION UNDER SECTION 7, AND FOR PROJECT DELIVERY REQUIREMENTS AS APPLICABLE UNDER SECTION 10. A FACILITY FOR WHICH ALL OF ITS OPERATING ROOM(S) ARE HYBRID OR/CCL(S) SHALL NOT HAVE 0.5 EXCLUDED FROM ITS INVENTORY OF CARDIAC CATHETERIZATION LABORATORIES FOR THE PURPOSES OF COMPUTING THE PROCEDURE EQUIVALENTS PER ROOM FOR EXPANSION UNDER SECTION 6. A facility will not be limited to the number of hybrid OR/CCL(S)s within a single licensed facility.

- 5. Section 10: Updated project delivery requirements as necessary:
 - (2)(g) EACH PHYSICIAN CREDENTIALLED BY A PRIMARY PCI OR AN ELECTIVE PCI HOSPITAL TO PERFORM LEFT-SIDED ABLATIONS SHALL PERFORM, AS THE PRIMARY OPERATOR, AN AVERAGE OF AT LEAST 50 ADULT LEFT-SIDED ABLATION SESSIONS PER YEAR AVERAGED OVER THE MOST RECENT TWO YEARS STARTING IN THE SECOND 12 MONTHS AFTER BEING CREDENTIALLED. THIS TWO-YEAR AVERAGE WILL BE EVALUATED ON A ROLLING BASIS ANNUALLY THEREAFTER. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS ADULT LEFT-SIDED ABLATION SESSIONS PERFORMED BY THAT PHYSICIAN IN ANY COMBINATION OF FACILITIES. PHYSICIANS FALLING BELOW THIS VOLUME REQUIREMENT MUST BE PLACED ON A FOCUSED PROFESSIONAL PRACTICE EVALUATION (FPPE) PLAN, WHICH MUST INCLUDE AN INDEPENDENT REVIEW OF LEFT-SIDED ABLATION SESSIONS BY AN APPROPRIATE DESIGNEE, TO ENSURE QUALITY OUTCOMES ARE MAINTAINED. IN THE EVENT A PHYSICIAN DOES NOT PERFORM CARDIAC CATHETERIZATION PROCEDURES ON A TEMPORARY OR PERMANENT BASIS FOR A PERIOD OF 3 MONTHS OR MORE, THE PHYSICIAN LEFT SIDED ABLATION VOLUME WILL BE ANNUALIZED ON THE 24-MONTH PERIOD PRECEDING THE ABSENCE.
 - (h) EACH PHYSICIAN CREDENTIALLED BY AN ELECTIVE PCI HOSPITAL TO PERFORM CORONARY ATHERECTOMY PROCEDURES SHALL PERFORM, AS THE PRIMARY OPERATOR, AN AVERAGE OF AT LEAST 10 CORONARY ATHERECTOMY PROCEDURES PER YEAR AVERAGED OVER THE MOST RECENT TWO YEARS STARTING IN THE SECOND 12 MONTHS AFTER BEING CREDENTIALLED. THIS TWO -YEAR AVERAGE WILL BE EVALUATED ON A ROLLING BASIS ANNUALLY THEREAFTER. THE ANNUAL CASE LOAD FOR A PHYSICIAN MEANS CORONARY ATHERECTOMY PROCEDURES PERFORMED BY THAT PHYSICIAN IN ANY COMBINATION OF FACILITIES. PHYSICIANS FALLING BELOW THIS VOLUME REQUIREMENT MUST BE PLACED ON A FOCUSED PROFESSIONAL PRACTICE EVALUATION (FPPE) PLAN, WHICH MUST INCLUDE AN INDEPENDENT REVIEW OF ALL CORONARY ATHERECTOMY PROCEDURES BY AN APPROPRIATE DESIGNEE, TO ENSURE QUALITY OUTCOMES ARE MAINTAINED. IN THE EVENT A PHYSICIAN DOES NOT PERFORM CARDIAC CATHETERIZATION PROCEDURES ON A TEMPORARY OR PERMANENT BASIS FOR A PERIOD OF 3 MONTHS OR MORE, THE PHYSICIAN CORONARY ATHERECTOMY PROCEDURE VOLUME WILL BE ANNUALIZED ON THE 24-MONTH PERIOD PRECEDING THE ABSENCE.
 - (jh) Each physician credentialed by an FSOF to perform CIED procedures shall meet the following criteria:
 - (i) performed at least 75 device implants as the primary operator in the previous 24 months;

- (ii) has at least 2 years of post-fellowship experience as an implanter;
 - (iii) is cardiology board certified for permanent pacemaker implants;
 - (iv) is CARDIOLOGY OR EP board certified for ICD implants; and
 - (v) has active privileges for implanting devices, moderate sedation, and admitting at the hospital identified in Section 4(3)(b).
 - (k) EACH PHYSICIAN CREDENTIALLED BY AN ELECTIVE PCI HOSPITAL TO PERFORM LEFT-SIDED ABLATIONS SHALL MEET THE FOLLOWING CRITERIA:
 - (i) HAS PERFORMED AT LEAST 150 ABLATION PROCEDURES AS THE PRIMARY OPERATOR IN THE PREVIOUS 24 MONTHS;
 - (ii) HAS AT LEAST 2 YEARS OF POST-FELLOWSHIP EXPERIENCE;
 - (iii) IS EP BOARD CERTIFIED AND:
 - (iv) HAS ACTIVE PRIVILEGES FOR PERFORMING ABLATIONS AND ADMITTING AT THE HOSPITAL IDENTIFIED IN SECTION 4(1).
 - (l) EACH PHYSICIAN CREDENTIALLED BY AN ELECTIVE PCI HOSPITAL WITHOUT ON-SITE OHS TO PERFORM CORONARY ATHERECTOMY SHALL MEET THE FOLLOWING CRITERIA:
 - (i) HAS PERFORMED A TOTAL OF AT LEAST 50 CORONARY ATHERECTOMY PROCEDURES AS THE PRIMARY OPERATOR POST-FELLOWSHIP;
 - (ii) HAS AT LEAST THREE YEARS OF EXPERIENCE AS THE PRIMARY OPERATOR FOR CORONARY ATHERECTOMY PROCEDURES POST-FELLOWSHIP; AND
 - (iii) IS BOARD CERTIFIED IN INTERVENTIONAL CARDIOLOGY
 - (m) EACH PHYSICIAN CREDENTIALLED TO PERFORM RIGHT-SIDED ABLATIONS SHALL MEET THE FOLLOWING CRITERIA:
 - (i) HAS PERFORMED AT LEAST 150 ABLATION PROCEDURES AS THE PRIMARY OPERATOR IN THE PREVIOUS 24 MONTHS;
 - (ii) HAS AT LEAST 2 YEARS OF POST-FELLOWSHIP EXPERIENCE.
 - (iii) IS EP BOARD CERTIFIED FOR ABLATION; AND
 - (iv) HAS ACTIVE PRIVILEGES FOR PERFORMING ABLATIONS AND ADMITTING AT THE HOSPITAL IDENTIFIED IN SECTION 4(3)(B).
 - (4)(a)(ii) 150 procedure equivalents in the category of adult ~~diagnostic~~ cardiac catheterization procedures, EXCLUDING PERIPHERAL, for a hospital in a rural or micropolitan county.
 - (ix) 200 adult PCI procedures for an elective PCI service without on-site OHS service located in a hospital WITHIN A METROPOLITAN COUNTY or FSOF.
 - (x) 100 ADULT PCI PROCEDURES FOR AN ELECTIVE PCI SERVICE WITHOUT ON-SITE OHS SERVICE LOCATED IN A HOSPITAL LOCATED WITHIN A RURAL OR MICROPOLITAN COUNTY.
 - (d) The applicant ~~FACILITY~~hospital shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.
 - (6) Compliance with all of the following requirements for FSOFs AND HOSPITALS WITHOUT ON-SITE OHS SERVICE, providing CIED procedures:
- 6. Technical edits:
- Section 10: (7) 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).

- Section 13: Proposed projects reviewed under these standards shall not be subject to comparative review. These CON Review Standards supersede and replace the CON Review Standards for Cardiac Catheterization Services approved by the CON Commission on JUNE 17, 2021~~September 20, 2018~~ and effective on SEPTEMBER 22, 2021~~December 26, 2018~~.
- 7. Section 11: Update the methodology for computing cardiac catheterization equivalents table:

Procedure	Description	Procedure equivalent	
		Adult	Pediatric
Diagnostic cardiac catheterization/peripheral session	Right heart catheterization, left heart catheterization, coronary angiography, coronary artery bypass graft angiography, intracoronary administration of drugs, fractional flow reserve (FFR), intra-coronary imaging [intravascular ultrasound (IVUS), optical coherence tomography (OCT)] when performed without a therapeutic procedure, cardiac biopsy , intra-cardiac echocardiography (ICE), diagnostic electrophysiology study, angiography in the peripheral arterial or venous circulation	1.5	2.7
Therapeutic cardiac catheterization session	PCI, pericardiocentesis, CARDIAC ABLATION, CARDIAC BIOPSY, CORONARY ATHERECTOMY, STRUCTURAL HEART PROCEDURES, AND/OR PACEMAKER, ICD, LEAD, OR GENERATORS PROCEDURES pacemaker implantation, ICD implantation (endovascular or subcutaneous), pacemaker/ICD generator change, pacemaker/ICD lead revision, cardiac ablation (excluding AF/VT), and/or structural heart procedure (excluding those listed below), and AS WELL AS IABP, Impella, ECMO, or TandemHeart when this is the only therapeutic procedure	2.7	4.0

The revisions to the CON Review Standards for Magnetic Resonance Imaging (MRI) Services received final approval by the CON Commission on June 12, 2025 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 August 27, 2025. The final language changes

include the following:

- 1. Section 2(1) definitions were modified and added as follows:
 - (uu) "SOLE COMMUNITY HOSPITAL OR "SCH" MEANS A HOSPITAL DESIGNATED BY CMS PURSUANT TO 42 CFR 412.92.
 - (ww)~~(vv)~~ "Teaching facility" means a licensed hospital site, or other location, that provides either fixed or mobile MRI services and at which residents or fellows of a training program in diagnostic radiology ENGAGE IN THE CARE OF A PATIENT (INCLUDING PROTOCOLING/INTERPRETATIONS OF STUDIES), AND that is approved by the Accreditation Council on Graduate Medical Education or American Osteopathic Association, are assigned. A TEACHING FACILITY SHALL BE IDENTIFIED AS MEETING THE DEFINITION IF AT LEAST ONE (1) OF THE FOLLOWING IS TRUE:
 - (i) THE PARTICIPATING HOSPITAL SITE OR OTHER LOCATION'S FACILITY NAME IS LISTED ON THE ACCREDITATION COUNCIL ON GRADUATE MEDICAL EDUCATION OR AMERICAN OSTEOPATHIC ASSOCIATION'S ACCREDITATION LETTER AS HAVING A TRAINING PROGRAM IN DIAGNOSTIC RADIOLOGY.
 - (ii) THE PARTICIPATING HOSPITAL SITE OR OTHER LOCATION IS OWNED BY AN ENTITY THAT IS LISTED ON THE ACCREDITATION COUNCIL ON GRADUATE MEDICAL EDUCATION OR AMERICAN OSTEOPATHIC ASSOCIATION'S ACCREDITATION LETTER AS HAVING A TRAINING PROGRAM IN DIAGNOSTIC RADIOLOGY.
- 2. Updated language to consider MRI in Rural and micropolitan statistical areas.
 - Section 2(mm)(i): in the case of a proposed fixed MRI service or unit, the geographic area within a 20-mile radius from the proposed site if the proposed site is not in a rural or micropolitan statistical area county and a 75-mile radius from the proposed site if the proposed site is in a rural or micropolitan statistical area county, or is designated by the Centers for Medicare and Medicaid Services (CMS) as a Critical Access Hospital (CAH)-, OR SOLE COMMUNITY HOSPITAL (SCH).
 - (ii) in the case of a proposed mobile MRI service or unit, except as provided in subsection (iii), the geographic area within a 20-mile radius from each proposed host site if the proposed site is not in a rural or micropolitan statistical area county and within a 75-mile radius from each proposed host site if the proposed site is in a rural or micropolitan statistical area county, or is designated by the Centers for Medicare and Medicaid Services (CMS) as a Critical Access Hospital (CAH)-, OR SOLE COMMUNITY HOSPITAL (SCH).
 - Section 3(2)(b)(iii)(B): The applicant hospital operates an emergency room that provides 24-hour emergency care services and at least 20,000 visits if located in a metropolitan statistical area county, or 10,000 visits if located in a rural or micropolitan statistical area or is designated by the Centers for Medicare and Medicaid Services (CMS) as a Critical Access Hospital (CAH)-, OR SOLE COMMUNITY HOSPITAL (SCH). within the most recent 12-month period for which data, verifiable by the Department, is available.
 - (4)(a) 600 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, for a proposed host site that is not located in a METROPOLITAN STATISTICAL AREA rural or micropolitan statistical area county, or
 - (b) 400 available MRI adjusted procedures from within the same planning area for a proposed host site that is located in a rural or micropolitan statistical area

- county, or is designated by the Centers for Medicare and Medicaid Services (CMS) as a Critical Access Hospital (CAH), OR SOLE COMMUNITY HOSPITAL (SCH) and
- Section 4(4)(c): The proposed new site is within a 5-mile radius of the existing site for a metropolitan statistical area county or within a 10-mile radius for a rural or micropolitan statistical area county or is designated by the Centers for Medicare and Medicaid Services (CMS) as a Critical Access Hospital (CAH). OR SOLE COMMUNITY HOSPITAL (SCH).
 - Section 13(4): The applicant hospital is designated as a level I or II trauma facility by the American College of Surgeons and has been certified as a Comprehensive Stroke Center by the Joint Commission, the Accreditation Commission for Health Care, Inc., or Det Norske Veritas or has cared for more than 500 acute stroke patients in the most recent 12-month period if located in a metropolitan county, or 300 acute stroke patients in the most recent 12-month period if located in a rural or micropolitan county, OR IS DESIGNATED BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) AS A CRITICAL ACCESS HOSPITAL (CAH), OR SOLE COMMUNITY HOSPITAL (SCH).
 - Section 15(4)(a)(iv): Each mobile host site in a rural or micropolitan statistical area county or designated by the Centers for Medicare and Medicaid Services (CMS) as a Critical Access Hospital (CAH), OR SOLE COMMUNITY HOSPITAL (SCH), shall have provided at least a total of 400 adjusted procedures during its second 12 months of operation, and annually thereafter, from all mobile units providing services to the site. Each mobile host site ~~not in a rural or micropolitan~~ IN A METROPOLITAN statistical area county shall have provided at least a total of 600 adjusted procedures during its second 12 months of operation and annually thereafter, from all mobile units providing services to the site.
 - Section 16(2)(a): For a site located in a rural or micropolitan statistical area county or a site designated by the Centers for Medicare and Medicaid Services (CMS) as a Critical Access Hospital (CAH) number of MRI-adjusted procedures shall be multiplied by a factor of 1.4.
- 3. Updated Section 4 to add MRI mobile host site has been in operation for at least 12 months:
- (4)(b) The MRI mobile host site to be relocated has been in operation FOR AT LEAST 12 MONTHS AT ITS CURRENT SITE as of the date an application is submitted to the Department.
- 4. Updated Section 9 to include additional criteria allowing non-surgical diagnostic studies to be performed on an IMRI unit:
- Section 9(6)(a): the patient has been admitted to an inpatient unit; or
 - (b) the patient is having the study performed on an outpatient basis, but is in need of general anesthesia or deep sedation as defined by the American Society of Anesthesiologists; OR
 - (c) THE PATIENT IS HAVING A DIAGNOSTIC OR THERAPUTIC PROCEDURE PERFORMED USING AN IMRI UNIT TO TARGET SPECIFIC AREAS WITHIN THE BODY, INCLUDING BIOPSIES, INJECTIONS, ULTRASOUNDS, OR OTHER PROCEDURES THAT REQUIRE ACCURATE LOCALIZATION OF TISSUES OR STRUCTURES.
- 5. Updated Section 15(2) to clarify the term “immediately available”.
- (e) The applicant shall have, within the MRI unit/service, equipment and supplies to handle clinical emergencies that might occur in the unit. MRI service staff will be trained in CPR and other appropriate emergency interventions. A physician,

~~NURSE PRACTITIONER, OR PHYSICIAN ASSISTANT, OR REGISTERED NURSE TRAINED IN THE MANAGEMENT OF HYPERSENSITIVITY AND PHYSIOLOGIC DRUG REACTIONS TO MRI CONTRAST MATERIALS SHALL BE ON-SITE WHEN PATIENTS ARE RECEIVING INTRAVENOUS CONTRAST. shall be on-site, in, or immediately available to the MRI unit at all times when patients are undergoing scans.~~

- 6. Updated Section 15 with mobile host site patient safety requirements:
 - (7)(b) EACH HOST FACILITY MUST PROVIDE A PROPERLY PREPARED PARKING PAD FOR THE MOBILE MRI SCANNER OF SUFFICIENT LOADBEARING CAPACITY TO SUPPORT THE VEHICLE, A WAITING AREA FOR PATIENTS, AND A MEANS FOR PATIENTS TO ENTER THE VEHICLE WITHOUT GOING OUTSIDE (SUCH AS A CANOPY OR ENCLOSED CORRIDOR). EACH HOST SITE FACILITY MUST ALSO PROVIDE THE CAPABILITY FOR PROCESSING THE IMAGES AND MAINTAINING THE CONFIDENTIALITY OF PATIENT RECORDS. A COMMUNICATION SYSTEM MUST BE PROVIDED BETWEEN THE MOBILE VEHICLE AND EACH HOST SITE FACILITY TO PROVIDE FOR IMMEDIATE NOTIFICATION OF EMERGENCY MEDICAL SITUATIONS.
- 7. Updated Section 16 with additive factors for patients with implants or other metallic foreign bodies:
 - (1)(k): FOR EACH MRI VISIT INVOLVING AN AIMD/FOREIGN BODY SCAN, ONLY ONE OF THE FOLLOWING SHALL BE ADDED TO THE BASE VALUE AND SHALL ONLY BE REPORTED FOR THE FIRST MRI PROCEDURE IF THE MRI VISIT INVOLVES MORE THAN ONE MRI PROCEDURE:
 - (i) 0.75 SHALL BE ADDED TO THE BASE VALUE FOR A LOW COMPLEXITY AIMD/FOREIGN BODY SCAN; OR,
 - (ii) 1.25 SHALL BE ADDED TO THE BASE VALUE FOR A MEDIUM COMPLEXITY AIMD/FOREIGN BODY SCAN; OR,
 - (iii) 1.50 SHALL BE ADDED TO THE BASE VALUE FOR A HIGH COMPLEXITY AIMD/FOREIGN BODY SCAN; OR,
 - (iv) 1.75 SHALL BE ADDED TO THE BASE VALUE FOR A PATIENT IMPLANTED WITH MULTIPLE AIMD'S, AND/OR AN MRI PROCEDURE PERFORMED "OFF-LABEL".
 - (v) DEFINITIONS:
 - (A) ACTIVE IMPLANT MEDICAL DEVICE (AIMD): AN IMPLANTED DEVICE THAT REQUIRES AN EXTERNAL POWER SOURCE TO OPERATE. ACTIVE IMPLANTS OFTEN REQUIRE THE MRI UNIT TO OPERATE AT A LOWER ENERGY LEVEL AND/OR OVER A LONGER PERIOD TO COMPENSATE FOR THE WHOLE-BODY SPECIFIC ABSORPTION RATE (SAR) OR B1+RMS IMAGING LIMITS AS DEFINED IN THE IMPLANT'S FDA LABELING FOR MRI IMAGING. EXAMPLES INCLUDE CARDIAC IMPLANTABLE ELECTRONIC DEVICES (CIEDS), STIMULATORS, COCHLEAR DEVICES, AND IMPLANTED INFUSION PUMPS.
 - (B) FOREIGN BODY: AN ABNORMAL METALLIC OBJECT THAT IS PRESENT WITHIN THE HUMAN BODY AS A RESULT OF AN INJURY. METAL FOREIGN BODIES MAY ALSO BE PRESENT IF THEY ARE INGESTED, INHALED, OR INSERTED. THESE ARE NOT CONSIDERED MEDICAL DEVICES OR IMPLANTS BUT ARE SUBJECT TO AN MRI EXAMINATION SAFETY EVALUATION.
 - (C) MRI EXAMINATION SAFETY EVALUATION: A PATIENT EVALUATION WHERE AN IMPLANT AND/OR METALLIC FOREIGN BODY IS ASSESSED

FOR SAFETY BY A CERTIFIED MRI TECHNOLOGIST, LICENSED PHYSICIST, RADIOLOGIST, OR OTHER APPROPRIATELY TRAINED HEALTH CARE PROFESSIONAL. THIS INCLUDES IDENTIFICATION AND VERIFICATION OF IMPLANT COMPONENTS FROM APPROPRIATE SOURCES (E.G., SURGICAL REPORTS, IMAGING REPORTS, MEDICAL DEVICE DATABASES, DEVICE VENDORS, REVIEW OF PRIOR IMAGING), ANALYZING CURRENT MRI CONDITIONAL STATUS OF INDIVIDUAL COMPONENTS AND SYSTEMS, AND CONSULTING PUBLISHED PROFESSIONAL GUIDANCE WITH A WRITTEN REPORT.

- (D) “OFF-LABEL” IMAGING OF AN ACTIVE IMPLANT: DEFINED AS IMAGING UNDER CONDITIONS THAT CONTRADICT OR EXCEED THE FDA-APPROVED LABELING FOR MRI IMAGING OR IMAGING AN ACTIVE IMPLANT WHEN LABELING DOES NOT EXIST. THIS SHOULD BE PERFORMED IF DEEMED APPROPRIATE AFTER CONSIDERING THE RISKS AND BENEFITS OF THE PROCEDURE.
- (E) SPECIFIC ABSORPTION RATE (SAR): THE DOSIMETRIC TERM USED TO ESTIMATE THE RATE OF ABSORPTION OF RADIOFREQUENCY (RF) ENERGY BY HUMAN TISSUE IN MRI. THE MOST COMMONLY USED SAR METRIC PRESENTED BY THE SCANNER IS THE WHOLE BODY AVERAGED VALUE. IT IS EXPRESSED IN WATTS PER KILOGRAM (W/KG) ON AN MRI SYSTEM.
- (F) B1+RMS (ROOT-MEAN-SQUARE): THE VALUE OF THE TRANSMITTED RADIOFREQUENCY (RF) MAGNETIC FIELD DELIVERED TO HUMAN TISSUE WITHIN A GIVEN MRI IMAGING SEQUENCE AVERAGED OVER 10 SECONDS. IT IS MEASURED IN MICRO-TESLA (μ T).
- (G) HIGH COMPLEXITY AIMD / FOREIGN BODY SCAN: AN MRI VISIT INVOLVING A PATIENT IMPLANTED WITH AN ACTIVE IMPLANT THAT HAS UNDERGONE AN MRI EXAMINATION SAFETY EVALUATION AND CAN BE IMAGED WHEN OPERATING THE MRI UNIT AT A LOWER ENERGY LEVEL TO MEET THE IMPLANT’S FDA LABELING FOR MRI IMAGING. APPLIES WHEN MAXIMUM WHOLE-BODY SAR IS 0.1 – 1.0 W/KG OR B1+RMS IS 2.0 μ T OR BELOW AND A TOTAL IMAGING TIME LIMIT EXISTS, AND/OR AT LEAST ONE OF THE FOLLOWING ROLES ARE REQUIRED TO ASSIST TO ENSURE SAFE IMAGING: ONSITE OR REMOTE PHYSICIAN SPECIALIST, ONSITE OR REMOTE PHYSICIST, ONSITE OR REMOTE VENDOR FIELD REP, AN ONSITE ADVANCED CARDIOVASCULAR LIFE SUPPORT (ACLS) OR OTHER APPROPRIATELY TRAINED PERSONNEL.
- (H) MEDIUM COMPLEXITY AIMD / FOREIGN BODY SCAN: AN MRI VISIT INVOLVING A PATIENT IMPLANTED WITH AN ACTIVE IMPLANT THAT HAS UNDERGONE AN MRI EXAMINATION SAFETY EVALUATION AND CAN BE IMAGED WHEN OPERATING THE MRI UNIT AT A LOWER ENERGY LEVEL TO MEET THE IMPLANT’S FDA LABELING FOR MRI IMAGING. APPLIES WHEN THE WHOLE-BODY SAR IS 1.1 – 2.0 W/KG OR B1+RMS IS 2.1 – 3.2 μ T, AND/OR A TOTAL IMAGING TIME LIMIT EXISTS.
- (I) LOW COMPLEXITY AIMD / FOREIGN BODY SCAN: AN MRI VISIT INVOLVING A PATIENT IMPLANTED WITH AN ACTIVE IMPLANT THAT HAS UNDERGONE AN MRI EXAMINATION SAFETY EVALUATION AND CAN BE SCANNED UNDER NORMAL OPERATING MODE AND/OR A PATIENT IMBEDDED WITH A METALLIC FOREIGN BODY FROM PRIOR INJURY THAT HAS BEEN DEEMED LOW RISK.

➤ 8. Other technical edits:

- Section 15(4)(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).
- Section 21(1): These CON review standards supersede and replace the CON Review Standards for MRI Services approved by the CON Commission on SEPTEMBER 15, 2022 ~~March 18, 2024~~ and effective JANUARY 26, 2023 ~~May 28, 2024~~.

The revisions to the CON Review Standards for Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services received final approval by the CON Commission on June 12, 2025 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 August 27, 2025. The final language changes include the following:

- 1. Technical edits:
 - Section 4: Replace an existing UESWL unit means (i) an equipment change of an existing UESWL unit, other than an upgrade, proposed by an applicant that results in that applicant operating the same number of UESWL units before and after the project completion. OR (ii) THE RENEWAL OF A LEASE. The term does not include an upgrade of an existing UESWL unit, changing a mobile UESWL unit to a fixed UESWL unit, or changing a fixed UESWL unit to a mobile UESWL unit. Replacement also means a change in the location of a fixed UESWL unit(s) from the existing site to a different site, OR a change in the geographic location of an existing fixed UESWL service and its unit(s) from an existing site to a different site.
 - (2) An applicant proposing to replace an existing UESWL unit(s), THAT DOES NOT INVOLVE A RENEWAL OF A LEASE, shall demonstrate one or more of the following:
 - Section 9(4)(d) 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).
 - Section 12(1): These CON review standards supersede and replace the CON review standards for urinary extracorporeal shock wave lithotripsy (UESWL) services approved by the CON Commission on ~~March 27, 2018~~ SEPTEMBER 19, 2019 and effective on ~~May 29, 2018~~ NOVEMBER 12, 2019.

The following review standards were reviewed by an informal workgroup or standard advisory committee (SAC) with anticipated completion in FY2026:

Psychiatric Beds and Services: The Commission took Final action at its September 18, 2025 meeting. The standards were sent to the governor and legislature for a 45-day review (with at least nine legislative session days), with anticipation to become effective during FY2026.

Cardiac Catheterization Services, Computed Tomography (CT) Scanner Services, Megavoltage Radiation Therapy (MRT) Services/Units, Positron Emission Tomography (PET) Scanner Services, Hospital Beds, Open Heart Surgery (OHS) Services, Nursing Home and Hospital Long-Term-Care Unit (NH-HLTCU) Beds, Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services, Psychiatric Beds and Services, Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services, Magnetic Resonance Imaging (MRI) Services, and

Surgical Services: A workgroup reviewed the standards during FY2025 to update the county designations for rural and metropolitan counties throughout the standards. The Commission took proposed action at their September 18, 2025 meeting. A public hearing and final action will be held during FY2026.

Neonatal Intensive Care Beds/Services (NICU) and Special Newborn Nursing Services: A workgroup convened during FY2025 to review the standards and will conclude during FY2026.

Heart, Lung, and Liver (HLL) Transplantation Services was reviewed by a SAC during FY2025. The Commission took proposed action at the June 12, 2025, commission meeting. At the Sep 18, 2025, CON meeting, the Commission disapproved final action and moved to seat another SAC to review the cost and quality implications of adding a 4th liver location in the State of Michigan. A SAC will be convened during FY2026.

Computed Tomography (Ct) Scanner Services are being reviewed by a SAC.

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

APPENDIX I - CERTIFICATE OF NEED COMMISSION

Amy Milewski, MD, CON Commission Chairperson
Debra Guido-Allen, RN, CON Commission Vice Chairperson
Amy Engelhardt-Kalbfleisch, DO
Eric Ferguson, MD
Greg Salwin
Mark DeLano, MD
Robert Gibson
Karen Cheeseman
Daniel Velez
Tatiana Grant

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