DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH ADMINISTRATION

BUREAU OF EMERGENCY PREPAREDNESS, EMS, AND SYSTEMS OF CARE

STATEWIDE STEMI SYSTEM

(By authority conferred on the director of the department of health and human services by sections 2233, 9227, and 20910 of the public health code, 1978 PA 368, MCL 333.2233, 333.9227 and 333.20910, and section 1186 of article 6 of 2022 PA 166.)
R 330.201, R 330.202, R 330.203, R 330.204, R 330.205, R 330.206, R 330.207, R 330.208, R 330.209, R 330.210, R 330.211, R 330.212, R 330.213, and R 330.214 are added to the Michigan Administrative Code, as follows:

PART 1. GENERAL PROVISIONS

R 330.201 Definitions; A to E.

Rule 1. As used in these rules:

(a) “ACC” means the American College of Cardiology.

(b) “Accreditation” means a process that a healthcare facility undergoes to demonstrate compliance with standards developed by a department-approved nationally recognized professional accrediting organization.

(c) “Administrative hearing” means a hearing conducted pursuant to the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328.

(d) “AHA” means the American Heart Association.

(e) “Certification” means a process that a healthcare facility undergoes to meet predetermined standards of a department-approved nationally recognized professional certifying organization.

(f) “Code” means the public health code, 1978 PA 368, MCL 333.1101 to 333.25211.

(g) “Department” means the department of health and human services.

(h) “Designation” means a status that is conferred by the department on STEMI centers and facilities that have been verified by a nationally recognized professional accrediting and certifying organization.

(i) “Disciplinary action” means an action taken by the department against a healthcare facility or a regional STEMI network for failure to comply with the code, rules, or protocols approved by the department.

(j) “ECG” or "electrocardiogram" means a test that measures the electrical activity of a heartbeat.

(k) “EMS” means emergency medical services.

History: 2023 MR 22, Eff. Nov. 9, 2023.

R 330.202 Definitions; F to N.

Rule 2. As used in these rules:

(a) “Healthcare facility” means a facility licensed under section 20141 or 21511 of the code, MCL 333.20141 and 333.21511, that operates a service for treating emergency patients, 24 hours per day, 7 days per week.

(b) “Hold itself out” means an agency, healthcare facility, or STEMI care center or facility advertises, announces, or charges specifically for providing STEMI care services.

(c) “Inter-facility STEMI transfer” means identifying the group of STEMI patients that require additional STEMI resources with the goal of providing optimal care by the timely transfer of these patients to an appropriate level of care to optimize outcome.

(d) “MCA” or "medical control authority" means an organization designated by the department to provide medical control.

(e) “MCA area” means the geographic area comprised of a county, group of counties, or parts of an individual county, as designated by the department.

(f) “Medical control” means the supervision and coordination of emergency medical services through an MCA, as prescribed, adopted, and enforced through department-approved protocols, within an emergency medical system.

(g) “Non-designated healthcare facility” means a healthcare facility that has chosen not to be a part of this state’s STEMI system of care or a healthcare facility that the department has not designated as a STEMI center or facility.

History: 2023 MR 22, Eff. Nov. 9, 2023.

R 330.203 Definitions; P to V.

Rule 3. (1) As used in these rules:

(a) “PCI” or “percutaneous coronary intervention” means a procedure used to open or widen a narrowed or blocked coronary artery to restore the blood flow that supplies the heart and is usually performed on an emergency basis for a STEMI patient.

(b) “Protocol” means a patient care standard, standing order, policy, or procedure for providing emergency medical services that is established by an MCA and approved by the department under section 20919 of the code, MCL 333.20919.

(c) “Provisional” means a one-time temporary time-limited status conferred on a facility by the department that most closely matches the current level of care based on the published criteria for accreditation or certification for which it is applying.

(d) “PSRO” or “professional standards review organization” means a committee established by a life support agency or an MCA for the purpose of improving the quality of medical care, as provided in section 1 of 1967 PA 270, MCL 331.531.

(e) “Quality improvement program” means actions taken by a life support agency, MCA, STEMI center or facility, or jointly between a life support agency, MCA, or STEMI center or facility with a goal of continuous improvement of medical care in accordance with the code. Actions must take place under a PSRO, as provided in sections 1 to 3 of 1967 PA 270, MCL 331.531 to 331.533.

(f) “Regional STEMI advisory council” means a committee established by a regional STEMI system whose function is to provide leadership and direction in matters related to STEMI system development in their region, and to monitor the performance of the STEMI agencies and healthcare facilities within the region, including, but not limited to,

the review of STEMI deaths and preventable complications, and it is comprised of the following:

(i) MCA personnel.

(ii) EMS personnel.

(iii) Life support agency representatives.

(iv) Healthcare facility representatives.

(v) Physicians.

(vi) Nurses.

(vii) Consumers.

(g) "Regional STEMI plan" means a written plan prepared by a regional STEMI advisory council, and approved by the regional STEMI system, that is based on minimum criteria established by the department.

(h) "Regional STEMI system" means an organized group comprised of the local MCA within a region that integrates into the existing regional trauma network and is responsible for appointing a regional STEMI advisory council and creating a regional STEMI plan.

(i) "Regional systems of care authority" means an organization recognized by the department that is comprised of MCAs within a region and is also approved as the regional trauma network, which provides clinical oversight for the regional trauma system, regional stroke system, and regional STEMI system within the region.

(j) "RPSRO" or regional PSRO means a committee established by the regional STEMI system for the purpose of improving the quality of STEMI care within a recognized STEMI region as provided in sections 1 to 3 of 1967 PA 270, MCL 331.531 to 331.533.

(k) "Statewide STEMI care advisory subcommittee" means a STEMI care advisory subcommittee that acts as the department's subject matter experts regarding the clinical and operational components of STEMI care.

(l) "Statewide STEMI registry" means a system for collecting data that the department manages, analyzes, and disseminates.

(m) "Statewide STEMI system of care" means a comprehensive and integrated arrangement of emergency services personnel, STEMI centers or facilities, equipment, services, communications, MCAs, and organizations necessary to provide STEMI care to all patients within a particular geographic region.

(n) "STEMI" means an ST-segment elevation myocardial infarction defined by symptoms of myocardial infarction associated with an ST-segment elevation on an ECG.

(o) "STEMI bypass" means to forego EMS transport of a patient to the nearest healthcare facility for a healthcare facility whose resources are more appropriate to the STEMI patient pursuant to direction given to pre-hospital emergency medical services by online medical direction or predetermined triage criteria as established by department-approved protocols.

(p) "STEMI care" means diagnostic evaluation, triage, acute intervention, emergency transport, and other acute care services for STEMI patients who potentially require emergent cardiac care, and may include education, risk reduction, and subacute STEMI management.

(q) "STEMI diversion" means the re-routing of a STEMI patient from a STEMI care center that has one or more of its essential resources currently functioning at maximum

capacity, or is otherwise unavailable, to an alternate STEMI care center to serve the best interests of the STEMI patient.

(r) "STEMI receiving center" means a healthcare facility designated by the department as having met the criteria set forth by a department-approved nationally recognized professional accrediting and certifying organization as having the resources to provide PCI, treatment, and referral for emergency STEMI patients 24 hours per day, 365 days per year.

(s) "STEMI referral facility" means a healthcare facility designated by the department as having met the criteria set forth by a department-approved nationally recognized professional accrediting/certifying organization as having the resources to provide treatment and referral services for STEMI patients 24 hours per day, 365 days per year.

(t) "STEMI response" means an individual who has been identified as a potential STEMI patient and requires the utilization of the STEMI system of care.

(u) "TJC" means the Joint Commission.

(v) "Triage" means classifying patients according to the severity of their medical conditions.

(w) "Verification" means an evaluation process conducted by a national professional accrediting and certifying organization, or the department, to verify resources and improve STEMI care.

(2) A term defined in the code has the same meaning when used in these rules.

History: 2023 MR 22, Eff. Nov. 9, 2023.

R 330.204 Powers and duties of department.

Rule 4. (1) The department, with the advice of the state EMS coordination committee and statewide STEMI care advisory subcommittee, shall do all the following:

(a) Implement an all-inclusive STEMI system throughout this state that allows for the care of all STEMI patients in an integrated system of healthcare in the pre-hospital and healthcare facility environments by personnel that are well trained and equipped to care for STEMI patients.

(b) Perform all the following:

(i) Establish regional systems of care authorities comprised of the MCAs in each region currently approved as regional trauma networks. The regional systems of care authority shall provide oversight for the regional trauma system, regional stroke system, and regional STEMI system.

(ii) Establish a statewide STEMI care quality improvement program using a statewide database.

(iii) Monitor the statewide STEMI system.

(iv) Ensure the coordination and performance of the regional STEMI systems.

(v) Set minimum standards for system performance and STEMI patient care.

(c) Develop a statewide process to establish regional STEMI systems comprised of the local MCAs, within a region, and in a manner that integrates the STEMI system into existing regional trauma, EMS, and medical control systems.

(d) Develop, implement, and maintain a state STEMI systems of care plan.

(e) Develop an in-state process for the verification of STEMI resources based on a department-approved nationally recognized professional certifying and accrediting organization's current standards if resources are available.

(f) Develop a statewide process for the designation of STEMI centers and facilities.

(g) Develop an appeals process for healthcare facilities to contest their designation determination.

(h) Establish state STEMI care recommendations and approve regional STEMI protocols that are established and adopted by the local MCAs.

(i) Recognize the established regional STEMI systems.

(j) Provide system oversight of the STEMI care provided in each region in accordance with the following:

(i)Regional STEMI systems must be integrated into the established regional systems of care authority composed of the collaborating local MCAs in a region.

(ii) The regional systems of care authority shall apply to the department for approval and recognition as a regional STEMI system. The department, with the statewide STEMI care advisory subcommittee and state EMS coordination committee, shall review the regional STEMI system application for approval every 3 years.

(iii) The establishment of the regional STEMI system does not limit the transfer or transport of STEMI patients between regions of this state.

(k) Require STEMI triage protocol that is established and adopted by local MCA and regional STEMI systems and developed based on triage criteria prescribed by the department on the recommendation of the statewide STEMI care advisory subcommittee and state EMS coordination committee, and following the procedures established by the department under section 20919(3) of the code, MCL 333.20919.

(l) Develop a statewide STEMI verification process based on the verification standards of a nationally recognized professional accrediting and certifying organization for a predetermined period of time.

(m) Establish a mechanism for periodic re-designation of STEMI centers and facilities.

(n) Develop a comprehensive statewide STEMI data collection system.

(o) Formulate recommendations for the development of performance improvement plans by the regional STEMI systems, consistent with those in R 330.211.

(p) Develop a process for STEMI system performance improvement, including responsibility for monitoring compliance with standards, maintaining confidentiality, and providing periodic review of STEMI center and facility standards set forth by nationally recognized professional review organizations as specified in R 330.206 and R 330.211.

(q) Develop a process for the evaluation of STEMI system effectiveness based on standards as specified in R 330.211.

(r) Coordinate and integrate appropriate STEMI risk reduction strategies and programs.

(s) Support the state STEMI system of care and provide resources to carry out its responsibilities and functions.

(t) Support the training and education needs and resources of STEMI care personnel throughout this state.

(2) The department may deny, suspend, or revoke designation of a STEMI center or facility upon a finding including, but not limited to, any one of the following:

(a) Failure to comply with the rules or healthcare facilities rules and regulations, or both.

(b) Willful preparation or filing of false reports or records.
(c) Fraud or deceit in obtaining or maintaining designation status.
(d) Failure to meet designation criteria established in these rules.
(e) Unauthorized disclosure of medical or other confidential information.
(f) Alteration or inappropriate destruction of medical records.
(g) The healthcare facility no longer has the resources required to comply with the current level of designation conferred.
(h) The healthcare facility no longer cares for STEMI patients.
(i) A department-approved STEMI care verification body has determined that the STEMI center or facility no longer meets the STEMI center or facility verification criteria.
(j) Identified deficiencies are not remediated in the allowable time frame.
(3) The department shall provide notice of disciplinary action including, but not limited to, intent to deny, suspend, or revoke STEMI center or facility designation and provide for an appeals process in accordance with the code and sections 71 to 87 of the administrative procedures act of 1969, 1969 PA 306, MCL 24.271 to 24.287.
(4) In developing a statewide STEMI system of care, the department shall consider all the following factors:
(a) Efficient implementation and operation.
(b) Decrease in morbidity and mortality.
(c) Cost effective implementation.
(d) Incorporation of national standards.
(e) Availability of funds for implementation.

History: 2023 MR 22, Eff. Nov. 9, 2023.

R 330.205 Participation in system; department prohibitions; coordinated care.

Rule 5. A healthcare facility may participate in the system to the extent or level that it commits the resources necessary for the appropriate management of STEMI patients. The department shall not limit the number of healthcare facilities that seek to qualify for a given level of STEMI designation under this system to ensure that all STEMI patients are served by a system of coordinated care.

History: 2023 MR 22, Eff. Nov. 9, 2023.

R 330.206 STEMI center or facility verification; designation and re-designation.

Rule 6. (1) A healthcare facility, which intends to hold itself out to provide STEMI care, shall obtain designation as a STEMI receiving center or STEMI referral facility. A healthcare facility shall not self-designate itself, advertise, or otherwise describe itself as a STEMI receiving center or STEMI referral facility without obtaining and maintaining that designation from the department. Facilities that are not designated by the department will be noted as non-designated healthcare facilities.
(2) The department shall re-designate the STEMI care capabilities of each STEMI center or facility based on verification and designation requirements in effect when the re-designation takes place.

(3) To obtain designation as a STEMI center or facility, the healthcare facility shall apply for designation to the department. A healthcare facility has a right to an administrative hearing if denied a specific STEMI center or facility level designation.

(4) The department shall designate the existing STEMI care resources of all participating healthcare facilities in the state, based on the following categories:

(a) A STEMI receiving center shall provide evidence of current certification or accreditation by a department-approved nationally recognized professional certifying and accrediting organization that the healthcare facility has the resources required to be certified as meeting all the criteria for a certified STEMI receiving center equivalent to a TJC-AHA comprehensive STEMI center or TJC-AHA primary heart attack center or an ACC chest pain center with PCI or a Corazon PCI/Catheterization program, or subsequent equivalent certification or accreditation as approved by the department with the advice of the STEMI advisory subcommittee, pursuant to R 330.204(1)(l), and all the following:

(i) Comply with data submission requirements in R 330.209 and R 330.210.

(ii) Participate in coordinating and implementing regional STEMI risk reduction plans.

(iii) Participate in the regional performance improvement process.

(iv) Provide staff assistance to the department for the state designation and verification process of STEMI referral centers when applicable pursuant to R 330.204(1)(l).

(b) A STEMI referral facility shall provide evidence of current certification or accreditation by a department-approved nationally recognized professional certifying and accrediting organization that the healthcare facility has the resources required to be certified as meeting all the criteria for a certified STEMI referral facility equivalent to a TJC-AHA acute heart attack ready center or an ACC non-PCI chest pain center or a Corazon chest pain center or subsequent equivalent certification or accreditation as approved by the department with the advice of the STEMI advisory subcommittee, pursuant to R 330.204(1)(l), and all the following:

(i) Comply with data submission requirements in R 330.209 and R 330.210.

(ii) Participate in coordinating and implementing regional STEMI risk reduction plans.

(iii) Participate in the regional performance improvement process.

(5) Healthcare facilities wishing to be re-designated as a STEMI receiving center shall independently obtain certification or accreditation by a department-approved nationally recognized professional certifying and accrediting organization at that level and comply with the standards that are incorporated by reference pursuant to R 330.204(1)(l), subrule (4)(a) of this rule, and all the following:

(a) Comply with data submission requirements in R 330.209 and R 330.210.

(b) Participate in coordinating and implementing regional STEMI risk reduction plans.

(c) Participate in the regional performance improvement process.

(d) Provide staff assistance to the department for the state designation and verification process of STEMI referral centers when applicable pursuant to R 330.204(1)(l).

(6) Healthcare facilities wishing to be re-designated as a STEMI referral facility shall independently obtain certification or accreditation by a department-approved nationally recognized professional certifying and accrediting organization at that level and comply with the standards that are incorporated by reference pursuant to R 330.204(1)(l) and R 330.206(4)(a) and all of the following:

(a) Comply with data submission requirements in R 330.209 and R 330.10.

(b) Participate in coordinating and implementing regional STEMI risk reduction plans.

(c) Participate in the regional performance improvement process.

(7) A hospital may apply to the department for one-time temporary, time-limited status as a provisional STEMI center or facility by submitting an application that includes evidence that the hospital meets the department-approved criteria for a provisional STEMI center or facility at the level that it is applying for. A hospital applying for provisional STEMI center or facility status requires the recommendation of the regional STEMI network system and notification to the statewide STEMI advisory subcommittee.

(8) The department may, with the advice and recommendations of the statewide STEMI care advisory subcommittee and state EMS coordination committee, modify the criteria or establish additional levels of STEMI care resources as appropriate to maintain an effective state STEMI system of care and protect the public welfare. The department shall not establish criteria for the purpose of limiting the number of healthcare facilities that qualify for a particular STEMI center or facility level of designation under these rules.

History: 2023 MR 22, Eff. Nov. 9, 2023.

R 330.207 Triage and transport.

Rule 7. (1) The department, with the advice and recommendations of the statewide STEMI care advisory subcommittee and state EMS coordination committee, shall develop recommendations, based on standards pursuant to R 330.204, R 330.212, R 330.213, and R 330.214 for protocols that are established and adopted by local MCAs for the triage, transport, and inter-facility STEMI transfer of STEMI patients to the appropriate STEMI centers and facilities.

(2) The standards under R 330.204, R 330.212, R 330.213, and R 330.214 for the triage, transport, and the inter-facility STEMI transfer of STEMI patients provide recommended minimum standards of care for protocols that are established and adopted by the local MCAs and that must be utilized in the care during transport of STEMI patients. On an annual basis, or as needed, the department shall review and update these recommended minimum standards with the advice and recommendations of the statewide STEMI care advisory subcommittee and state EMS coordination committee.

(3) The department, with the advice and recommendations of the statewide STEMI care advisory subcommittee and state EMS coordination committee, shall create regional STEMI systems that meet all of the following criteria and are responsible for developing triage and transport procedures within that geographical area:

(a) Each regional STEMI system must be integrated into the regional systems of care authority created within the existing trauma regions pursuant to R 325.132.

(b) Each regional STEMI system may create its own triage and transport criteria and protocols, destination criteria and protocols, and inter-facility STEMI transfer criteria and protocols, which are established and adopted by the local MCAs, provided they meet or exceed the standards that are incorporated by reference in these rules pursuant to R 330.212, R 330.213, and R 330.214, and are reviewed by the quality assurance task force and approved by the department.

This may include coordination of triage and transport criteria and protocols, which are established and adopted by local medical control, across geographic regions if in the best interest of providing optimal STEMI care to patients.

(c) STEMI care still must be provided to patients at healthcare facilities as necessary pursuant to 42 USC 1395dd and other applicable laws.

History: 2023 MR 22, Eff. Nov. 9, 2023.

R 330.208 STEMI care regions.

Rule 8. (1) The department, with the advice and recommendations of the statewide STEMI care advisory subcommittee and state EMS coordination committee, shall support the establishment and operational activities of the STEMI regions through the commitment of resources.

(2) Each region shall establish a regional STEMI system of care as prescribed and defined by R 330.201 to R 330.211.

(3) All MCAs within an area or region shall participate in the regional STEMI system of care, and life support agencies that care for STEMI patients shall be offered membership on the regional STEMI care advisory council. Regional STEMI care advisory councils must be operated in a manner that maximizes inclusion of their constituents. Regional STEMI care advisory councils must be operated in a manner that maximizes inclusion of their constituents and meets all of the following requirements:

(a) Not less than quarterly, a regional STEMI system of care shall submit evidence of ongoing activity, such as meeting notices and minutes, to the department. Annually, the regional STEMI care advisory council shall file a report with the department that describes ongoing progress toward regional STEMI care plan implementation and includes evidence that members of the regional STEMI care advisory council are currently involved in STEMI care.

(b) The regional STEMI system of care shall develop a regional STEMI care plan. The plan is subject to review by the statewide STEMI care advisory subcommittee and state EMS coordination committee and approval by the department.

(c) The department shall review the plan to ensure that it contains at a minimum, all of the following:

(i) All counties within the regional STEMI system have been included unless a specific county, or portion thereof, has been aligned within an adjacent STEMI system, and all healthcare entities, MCAs, and life support agencies have had an opportunity to participate in the planning process.

(ii) All of the following components have been addressed:

(A) STEMI risk reduction.

(B) Communications.

(C) Regional performance improvement.

(D) STEMI education.

(E) Infrastructure.

(F) Continuum of care.

(4) Each regional STEMI system of care shall appoint a RPSRO as defined in R 330.203(f).

(5) Each regional STEMI care advisory council shall develop performance improvement plans that are based on standards under R 330.211. The performance improvement plan shall be reviewed annually by the statewide STEMI care advisory subcommittee and state EMS coordination committee for recommendations to the department.

(6) Recommendations developed and proposed for implementation by a regional STEMI care advisory council must meet or exceed those that are established by the department with the advice and recommendations of the statewide STEMI care advisory subcommittee and state EMS coordination committee, as based on standards that are incorporated by reference in these rules, pursuant to R 330.204(1)(o) and R 325.204(1)(p).

(7) The department shall recognize the regional STEMI system once it approves a completed regional work plan. The regional STEMI system approval process must consist of the following phases:

(a) The first phase is the application phase, which begins with the submission to the department of a completed regional plan for the regional STEMI system.

(b) The second phase is the review phase, which begins after the receipt of the regional plan and ends with a department recommendation to approve the regional STEMI system.

(c) The third phase is the final phase, with the department making a final decision regarding the regional STEMI system plan. This phase also includes an appeal procedure for the denial of an approval of application in accordance with the department's administrative hearings requirements.

(8) If the application phase results in a recommendation to the department for approval by the statewide STEMI care advisory subcommittee and the state EMS coordination committee, and the department approves, then the department shall notify the regional STEMI system applicant of recommended action within 90 days after receipt by the department.

(9) Upon approval, a regional STEMI care advisory council shall implement the plan to include the following:

(a) Education of all entities about the plan components.

(b) On-going review of resources, process, and outcome data.

(10) The regional STEMI system approval is in effect for 3 years.

History: 2023 MR 22, Eff. Nov. 9, 2023.

R 330.209 Data collection.

Rule 9. (1) The department, with the advice and recommendations of the statewide STEMI care advisory subcommittee and state EMS coordination committee, shall develop and maintain a statewide STEMI registry. The registry must contain all the following:

(a) Standard STEMI data elements and definitions as a minimum set of elements for data collection, with the addition of elements as recommended by the statewide STEMI care advisory subcommittee and approved by the department, including subsequent amendments and editions.

(b) A plan for data including the following:

(i) Notifying partners of data dictionary changes and new iterations annually.

(ii) Defining the data validation process for designated STEMI center and facility data submissions to the statewide STEMI registry.

(iii) Participating in state data collaboration activities.

(iv) Establishing and maintain processes for the following:

(A) Submitting data related to STEMI responses to the statewide STEMI registry according to the data submission timelines.

(B) Monitoring national standards, regional issues, STEMI centers and facilities, and RPSROs to determine the need for additional data metrics needed for system function.

(C) For those STEMI responses that met the inclusion criteria identified for data submission, submitting the following data elements to the department:

(1) Standard STEMI data elements approved by the department with the advice and recommendations of the statewide STEMI care advisory subcommittee.

(2) Subsequent amendments or additions recommended by the statewide STEMI care advisory subcommittee.

(v) Developing annual reports using regional and state data defined by the statewide STEMI care advisory subcommittee, which assesses the state STEMI system of care and regional STEMI systems.

(vi) Evaluating and importing additional data from existing databases as needed.

(vii) Supporting and evaluating probabilistic and deterministic data linkages.

(2) The department shall support the data collection and analysis process.

(3) Both of the following apply to STEMI center or facility participation in data submission:

(a) All designated STEMI centers or facilities shall participate in data submission.

(b) Participation as appropriate in the RPSRO, as provided in sections 1 to 3 of 1967 PA 270, MCL 331.531 to 331.533.

History: 2023 MR 22, Eff. Nov. 9, 2023.

R 330.210 Statewide STEMI registry.

Rule 10. (1) The purpose of the STEMI registry is to collect and analyze system data to evaluate the delivery of STEMI care, develop STEMI risk reduction strategies, and provide resources for STEMI research and education.

(2) The department shall coordinate data collected by the STEMI centers or facilities and emergency medical service providers. The department shall develop and publish a data submission manual that specifies all of the following:

(a) Data elements and definitions, including the standards under R 330.209(1)(a), and the following:

(i) Definitions of what constitutes a reportable STEMI case.

(ii) Method of submitting data to the department.

(iii) Timetables for data submission.

(iv) Data submission format.

(v) Protections for individual record confidentiality.

(b) Notification to STEMI centers and facilities of the required registry data sets and to update the STEMI centers and facilities and providers, as necessary, when the registry data set changes.

(c) Specification of both the process and timelines for STEMI center and facility submission of data to the department.

(3) All healthcare facilities shall submit to the department STEMI data determined by the department to be required for the department's operation of the statewide STEMI registry. The department shall prescribe and provide both of the following:

(a) Standard reporting mechanisms to be used by all healthcare facilities.

(b) The form and content of records to be maintained and the information to be reported to the department.

(4) The department and regional STEMI care advisory councils shall use the STEMI registry data to identify and evaluate regional STEMI care and to prepare reports and analyses as requested by regional STEMI advisory councils, the statewide STEMI care advisory subcommittee, or the state EMS coordination committee.

History: 2023 MR 22, Eff. Nov. 9, 2023.

R 330.211 Regional performance improvement.

Rule 11. (1) Each regional STEMI system shall develop and implement a regional STEMI care performance improvement program. This program must include the standards that are incorporated by reference pursuant to R 330.204(1)(d), R 3330.204(1)(j), and R 330.208(5) and include the development of an annual process for reporting to the department a review of all region-wide policies, procedures, and protocols.

(2) Each regional STEMI system is responsible for monitoring, assessing, and evaluating the system to improve STEMI care, reduce death and disability, surveillance of STEMI incidence, and implementation of STEMI risk reduction initiatives.

(3) Each regional STEMI system shall appoint an RPSRO.

(4) Deviations from protocols established and adopted by local MCAs and approved by the department for STEMI patients must be addressed through a documented STEMI care performance improvement process established by a PSRO.

(5) Each regional STEMI care advisory council shall observe the confidentiality provisions of 45 CFR part 164, the health insurance portability and accountability act of 1996, Public Law 104-191, data confidentiality provisions under the code and any confidentiality provisions established by the RPSRO.

(6) The performance improvement program must include the standards under R 330.204(1)(p), R 330.208(5), and include all the following:

(a) Components of the regional STEMI care plan.

(b) Triage criteria and effectiveness.

(c) STEMI diversion and bypass.

(d) Data driven provision of care defined by available data metrics supported by the region, the statewide STEMI care advisory subcommittee, and the department.

(7) Each regional STEMI system is responsible for the ongoing evaluation of the system. Accordingly, each region shall develop a procedure for receiving information from the regional STEMI system constituents on the implementation of various components of that region’s STEMI system, and include the standards under R 330.204(1)(d) and R 325.208(5), and include all of the following:

(a) Components of the regional STEMI care plan.

(b) Triage criteria and effectiveness.

(c) STEMI diversion and bypass.

(d) Data analytics as defined by the department with the advice of the statewide STEMI care advisory subcommittee.

(8) Based upon information received by the region in the evaluation process, the region shall annually prepare a report containing results of the evaluation and a performance improvement plan. The report must be made available to all regional STEMI system constituents.

(9) The region shall ensure that all STEMI centers and facilities participate in this annual evaluation process and encourage all other hospitals that treat STEMI patients to do likewise. The region shall not release specific information related to an individual patient or practitioner. Aggregate system performance information and evaluation must be available for review.

History: 2023 MR 22, Eff. Nov. 9, 2023.

R 330.212 Destination protocols.

Rule 12. Local MCAs shall develop and submit STEMI patient destination protocols to the bureau of emergency preparedness, EMS, and systems of care for review by the statewide quality assurance task force appointed under section 20916 of the code, MCL 333.20916. After review and approval by the department, the MCAs must formally adopt and implement the protocol. The following factors must be used in evaluating destination protocols:

(a) STEMI patients must not be transported to a healthcare facility that does not participate in the state STEMI system of care unless there is no other reasonable alternative available.

(b) STEMI patients must be transported to the closest appropriate STEMI center or facility as identified in regional and local MCA protocols. In the event of a STEMI bypass, STEMI care must be provided to patients as necessary pursuant to 42 USC 1395dd or other applicable laws.

(c) If a STEMI receiving center is not within a reasonable distance from the incident scene, the STEMI patient must be transported to the closest appropriate STEMI referral facility.

(d) Each regional STEMI system shall make appropriate determinations for STEMI patient destination based on what is best for the patient.

(e) In areas of the state close to state borders, the most appropriate STEMI center or facility may be out of the state. If possible, transport STEMI patients within state borders. Local protocols must address this issue.

History: 2023 MR 22, Eff. Nov. 9, 2023.

R 330.213 STEMI patient inter-facility STEMI transfer protocols.

Rule 13. (1) All designated STEMI centers and facilities shall maintain inter-facility STEMI transfer protocols for patients that are consistent with regional and local MCA protocols and that are compliant with 42 USC 1395dd.

(2) All STEMI centers and facilities shall develop and implement formal policies based on published guidelines for the transfer of STEMI patients who need a higher level of care.

(3) STEMI patients must be transported to an appropriate hospital designated as a STEMI receiving center or STEMI referral facility.

History: 2023 MR 22, Eff. Nov. 9, 2023.

R 330.214 Criteria for transfer protocols; criteria.

Rule 14. Designated STEMI centers and facilities shall contact the department for current STEMI patient transfer guidelines.

History: 2023 MR 22, Eff. Nov. 9, 2023.