DEPARTMENT OF HEALTH AND HUMAN SERVICES

BUREAU OF EMERGENCY PREPAREDNESS, EMS, AND SYSTEMS OF CARE

EMS AND SYSTEMS OF CARE SECTION

STATEWIDE STROKE SYSTEM

Filed with the secretary of state on November 6, 2023

These rules become effective immediately after filing with the secretary of state unless adopted under section 33, 44, or 45a(9) of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(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 330.251, R 330.252, R 330.253, R 330.254, R 330.255, R 330.256, R 330.257, R 330.258, R 330.259, R 330.260, R 330.261, R 330.262, and R 330.263 are added to the Michigan Administrative Code, as follows:

PART 1. GENERAL PROVISIONS

R 330.251 Definitions; A to D.

Rule 1. As used in this part:

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

(b) "CMS" or "Centers for Medicare and Medicaid Services" means the program that is part of the United States Department of Health and Human Services.

(c) "Certification" means a process that a healthcare facility undergoes to demonstrate it has met predetermined standards of a department-approved, CMS-recognized professional certifying organization.

(d) "Code" means the public health code, 1978 PA 368, MCL 333.1101 to333.25211.

(e) "Department" means the department of health and human services.

(f) "Designation" means a status that is conferred by the department on stroke centers that are verified by a CMS-recognized professional certifying organization.

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

R 330.252 Definitions; E to O.

Rule 2. As used in this part:

(a) "EMS" means emergency medical services.

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

(c) “Hold itself out” means the agency, healthcare facility, or stroke care facility that advertises, announces, or charges specifically for providing stroke care.

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

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

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

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

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

R 330.253 Definitions; P to V.

Rule 3. (1) As used in this part:

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

(b) “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 certification for which it is applying.

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

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

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

(f) “Regional stroke plan” means a written plan prepared by a regional stroke advisory council, and approved by the regional stroke system, that is based on minimum criteria established by the department.

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

(h) “Regional stroke system” means an organized group comprised of the local MCA within a region, that integrates into existing regional trauma network or regional systems of care authority and is responsible for appointing a regional stroke advisory council and creating a regional stroke plan.

(i) “Regional systems of care authority” means an organization recognized by the department, comprised of approved MCAs within a region, 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) “Statewide stroke care advisory subcommittee” means a stroke care advisory subcommittee that acts as the department’s subject matter experts for the clinical and operational components of stroke care. As the system matures and signals readiness to capitalize on efficiencies, the system will merge into the statewide stroke care advisory subcommittee and the statewide STEMI care advisory subcommittee into the statewide cardiovascular care advisory subcommittee.

(k) “Statewide stroke registry” means a system for collecting data that the department manages, analyzes, and disseminates results.

(l) “Statewide stroke system of care” means a comprehensive and integrated arrangement of emergency services personnel, stroke centers, equipment, services, communications, MCAs, and organizations necessary to provide stroke care to all patients within a particular geographic region.

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

(n) “Stroke” means a cerebrovascular disease that causes a sudden interference in the blood supply to the brain causing neuronal injury with neurological symptoms. This occurs when a blood vessel in the brain is blocked by a clot or a vessel rupture.

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

(p) “Stroke care” means diagnostic evaluation, triage, acute intervention, emergency transport and other acute care services for stroke patients who potentially require emergent medical or surgical intervention or treatment, and may include education, risk reduction, and subacute stroke management.

(q) “Stroke center” means a healthcare facility designated by the department as having met the criteria set forth by a department-approved, CMS-recognized professional certifying organization as being any of the following:

(i) Level I or comprehensive stroke center.
(ii) Level II or thrombectomy capable stroke center.
(iii) Level III or primary stroke center.
(iv) Level IV or acute stroke ready center.

(r) “Stroke diversion” means the re-routing of a stroke patient from a stroke care facility that has 1 or more of its essential resources currently functioning at maximum capacity, or is

otherwise unavailable, to an alternate stroke care facility to serve the best interests of the stroke patient.

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

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

(u) "Verification" means an evaluation process conducted by a national professional certifying organization to verify resources and improve stroke care.

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

R 330.254 Powers and duties of department.

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

(a) Implement an all-inclusive stroke system throughout this state that allows for the care of all stroke 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 stroke patients.

(b) Perform all of 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 within the region.

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

(iii) Monitor the statewide stroke system.

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

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

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

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

(e) Develop a statewide process for the verification of stroke resources based on a stroke center's current certification by a department-approved, CMS-recognized professional certifying organization.

(f) Develop a statewide process for the designation of stroke centers.

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

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

(i) Recognize the regional stroke systems providing system oversight of the stroke care provided in each region of this state.

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

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

(l) The establishment of the regional stroke system does not limit the transfer or transport of stoke patients between regions of the state.

(m) Require stroke triage protocols, which are established and adopted by local MCA and regional stroke systems and developed based on triage criteria prescribed by the department on the recommendation of the statewide stroke 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.

(n) Develop a statewide stroke verification process based on the verification standards of a CMS recognized professional certifying organization for a predetermined period of time.

(o) Establish a mechanism for periodic re-designation of stroke centers.

(p) Develop a comprehensive statewide stroke data collection system.

(q) Formulate recommendations for the development of performance improvement plans by the regional stroke systems, consistent with those in R 330.260.

(r) Develop a process for stroke system performance improvement, including responsibility for monitoring compliance with standards, maintaining confidentiality, and providing periodic review of stroke center standards set forth by nationally recognized professional review organizations. The following standards are incorporated by reference in these rules, as specified in R 330.259, and R 330.260.

(t) Develop a process for the evaluation of stroke system effectiveness based on standards under R 330.260.

(u) Coordinate and integrate appropriate stroke risk reduction strategies and programs.

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

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

(2) The department may deny, suspend, or revoke designation of a stroke center on a finding including, but not limited to, any 1 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 stroke patients.

(i) A department-approved stroke care verification body has determined that the stroke center no longer meets their stroke center verification criteria.

(j) Identified deficiencies are not remediated in the allowable timeframe.

(3) The department shall provide a notice of disciplinary action including, but not limited to an intent to deny, suspend, or revoke a stroke center designation and provide for an appeals process under sections 71 to 87 of the administrative procedure act of 1969, 1969 PA 306, MCL 24271 to 24.287.

(4) In developing a statewide stroke care system, 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 money for implementation.

R 330.255 Stroke center verification; designation and re-designation.

Rule 5. (1) A healthcare facility that intends to hold itself out to provide stroke care shall not self-designate itself as a stroke center, advertise, or otherwise describe itself as a "designated stroke center" without obtaining and maintaining a designation from the department. Facilities that are not designated by the department will be noted as a non-designated healthcare facility.

(2) The department shall re-designate the stroke care capabilities of each stroke center based on verification and designation requirements in effect when the re-designation takes place.

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

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

(a) A level I or comprehensive stroke center shall provide evidence of current certification by a department-approved, CMS-recognized professional certifying organization that the healthcare facility has the resources required to be certified as meeting all the criteria, or subsequent equivalent certification as approved by the department, with the advice of the stroke advisory subcommittee, for an accredited comprehensive stroke center under R 330.254(1)(e). All the following apply to a level I stroke center:

(i) Comply with data submission requirements in R 330.258 and R 330.259.
(ii) Participate in coordinating and implementing regional stroke risk reduction plans.
(iii) Participate in the regional performance improvement process.
(iv) Provide staff assistance to the department for the designation and verification process of stroke centers when applicable under R 330.254(1)(e).

(b) A level II or thrombectomy capable stroke center shall provide evidence of current certification by a department-approved, CMS-recognized professional certifying organization that the healthcare facility has the resources required to be certified as meeting all the criteria, or subsequent equivalent certification as approved by the department with the advice of the stroke advisory subcommittee, for a certified thrombectomy capable stroke center under R 330.254 (1)(e), and all the following:

(i) Comply with data submission requirements in R 330.258 and R 330.259.
(ii) Participate in coordinating and implementing regional stroke risk reduction plans.
(iii) Participate in the regional performance improvement process.
(iv) Provide staff assistance to the department for the designation and verification process of stroke centers when applicable under R 330.254(1)(e).

(c) A level III or primary stroke center shall provide current certification by a department-approved, CMS-recognized professional certifying organization that the healthcare facility has the resources required to be certified as meeting all the criteria, or subsequent equivalent certification as approved by the department with the advice of the stroke advisory subcommittee, for a certified primary stroke center under R 330.254(1)(e), and all the following:

(i) Comply with data submission requirements in R 330.258 and R 330.259.
(ii) Participate in coordinating and implementing regional stroke risk reduction plans.
(iii) Participate in the regional performance improvement process.

(d) A level IV or acute stroke ready hospital stroke center shall provide current certification by a department-approved, CMS-recognized professional certifying organization that the healthcare facility has the resources required to be certified as meeting all the criteria, or subsequent equivalent certification as approved by the department with the advice of stroke advisory subcommittee, for a certified acute stroke ready hospital under R 330.254(1)(e). All the following apply to the level IV stroke center:

(i) Comply with data submission requirements in R 330.258 and R 330.259.

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

(iii) Participate in the regional performance improvement process.

(5) Healthcare facilities wishing to be re-designated as a level I or comprehensive stroke center shall independently obtain certification by a department-approved, CMS-recognized professional certifying organization at that level, and comply with the standards under R 330.254(1)(e), and all the following:

(a) Comply with data submission requirements in R 330.258 and R 330.259.

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

(c) Participate in the regional performance improvement process.

(d) Provide staff assistance to the department for the designation and verification process of stroke centers when applicable under R 330.254(1)(e).

(6) Healthcare facilities wishing to be re-designated as a level II or thrombectomy capable stroke center shall independently obtain certification by a department-approved, CMS-recognized professional certifying organization at that level, and comply with the standards under R 330.254(1)(e) and all of the following:

(a) Comply with data submission requirements in R 330.258 and R 330.259.

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

(c) Participate in the regional performance improvement process.

(d) Provide staff assistance to the department for the designation and verification process of stroke centers when applicable under R 330.254(1)(e).

(7) Healthcare facilities wishing to be re-designated as a level III or primary stroke center shall independently obtain certification by a department-approved, CMS-recognized professional certifying organization at that level and comply with the standards under R 330.254(1)(e), and the following:

(a) Comply with data submission requirements in R 330.258 and R 330.259.

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

(c) Participate in the regional performance improvement process.

(8) Healthcare facilities wishing to be re-designated as a level IV or acute stroke ready stroke center shall independently obtain certification by a department-approved CMS recognized professional certifying organization at that level and comply with the under R 330.254 (1)(e), and the following:

(a) Comply with data submission requirements in R 330.258 and R 330.259.

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

(c) Participate in the regional performance improvement process.

(9) A hospital may apply to the department for a one-time, temporary-time limited status as a provisional stroke center by submitting an application that includes evidence that the hospital meets the department-approved criteria for a provisional stroke center at the level that the hospital is applying. A hospital applying for provisional stroke center status requires the

recommendation of the stroke network system and notification to the statewide stroke advisory committee.

(10) The department may, with the advice and recommendations of the statewide stroke care advisory committee and state EMS coordination committee, modify the criteria or establish additional levels of stroke care resources as appropriate to maintain an effective state stroke 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 stroke center level of designation under these rules.

R 330.256 Triage and transport.

Rule 6. (1) The department, with the advice and recommendations of the statewide stroke care advisory subcommittee and state EMS coordinating committee, shall develop recommendations, based on standards in these rules, R 330.254, R 330.261, R 330.262, and R 330.263 for protocols that are established and adopted by local MCAs for the triage, transport, and inter-facility transfer of stroke patients to the appropriate stroke centers.

(2) The standards under R 330.254, R 330.261, R 330.262, and R 330.263 for the triage, transport, and the inter-facility transfer of stroke patients must provide recommended minimum standards of care for protocols that are established and adopted by local MCAs and that must be utilized in the care during transport of stroke 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 stroke care advisory subcommittee and the state EMS coordination committee.

(3) The department, with the advice and recommendations of the statewide stroke care advisory subcommittee and state EMS coordinating committee, shall create regional stroke systems that are responsible for developing triage and transport procedures within that geographical area. The triage and transport procedures must include both of the following:

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

(b) Each regional stroke system may create its own triage and transport criteria and protocols, destination criteria and protocols, and inter-facility transfer criteria and protocols, established and adopted by local MCAs, provided they meet or exceed the standards that are incorporated under R 330.261, R 330.262, and R 330.263, 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, established, and adopted by local MCAs, across geographic regions, if in the best interest of providing optimal stroke care to patients.

R 330.257 Stroke care regions.

Rule 7. (1) The department, with the advice and recommendations of the statewide stroke care advisory subcommittee and state EMS coordination committee, shall support the establishment and operational activities of the regional stroke system of care through the commitment of resources.

(2) Each region shall establish a regional stroke system of care as prescribed by this part.

(3) All MCA areas or regions shall participate in the regional stroke care system, and life support agencies that care for stroke patients shall be offered membership on the regional stroke care advisory council. Regional stroke care advisory councils must be operated in a manner that maximizes inclusion of their constituents. The following requirements must be met:

(a) Quarterly, a regional stroke system of care shall submit evidence of ongoing activity, such as meeting notices and minutes, to the department. Annually, the regional stroke system of care shall file a report with the department that describes ongoing progress toward regional stroke care plan implementation and includes evidence that members of the regional stroke care advisory council are currently involved in stroke care.

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

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

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

(ii) All the following components are addressed:

(A) Stroke risk reduction.

(B) Communications.

(C) Regional performance improvement.

(D) Stroke education.

(E) Infrastructure.

(F) Continuum of care.

(4) Each regional stroke system of care shall appoint a RPSRO.

(5) Each regional stroke care advisory council shall develop performance improvement plans that are based on standards under R 330.260. The statewide stroke care advisory subcommittee and state EMS coordination committee shall annually review the performance improvement plan and make recommendations to the department.

(6) Recommendations developed and proposed for implementation by a regional stroke care advisory council must meet or exceed those that are established by the department, with the advice and recommendations of the statewide stroke care advisory subcommittee and state EMS coordination committee, as based on standards under R 330.254(1)(n) and R 330.254(1)(o).

(7) The department shall recognize the regional stroke system once it approves a completed regional stroke plan. The regional stroke 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 stroke 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 stroke system.

(c) The third phase is the final phase, with the department making a final decision regarding the regional stroke 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 stroke care advisory subcommittee and the state EMS coordination committee, and the department approves, the department shall notify the regional stroke system applicant of recommended action within 90 days after receipt by the department.

(9) After approval, a regional stroke care advisory council shall implement the plan to include both the following:

(a) Education of all entities about the plan components.
(b) On-going review of resources, process, and outcome data.
(10) The regional stroke system approval is effective for 3 years.

R 330.258 Data collection.
Rule 8. (1) The department, with the advice and recommendations of the statewide stroke care advisory subcommittee and state EMS coordination committee, shall develop and maintain a statewide stroke registry. The registry must contain all the following:
(a) Standard stroke data elements and definitions as a minimum set of elements for data collection, with the addition of elements as recommended by the statewide stroke care advisory subcommittee and approved by the department, including subsequent amendments and editions.
(b) A plan for data that does all of the following:
(i) Notifies partners of data dictionary changes and new iterations annually.
(ii) Defines the data validation process for designated stroke center data submissions to the statewide stroke registry.
(iii) Participates in state data collaboration activities.
(iv) Establishes and maintains processes for the following:
(A) Submitting data related to stroke responses to the statewide stroke registry according to the data submission timelines.
(B) Monitoring national standards, regional issues, stroke center, and RPSRO to determine the need for additional data metrics needed for system function.
(C) For those stroke responses that met the inclusion criteria identified for data submission, submitting all of the following:
(1) Standard stroke data elements approved by the department with the advice and recommendations of statewide stroke care advisory subcommittee.
(2) Subsequent amendments or additions recommended by the statewide stroke care advisory subcommittee.
(v) Developing annual reports using regional and state data defined by the statewide stroke care advisory subcommittee that assess the state stroke system of care and regional stroke 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 stroke center participation in data submission:
(a) All designated stroke centers 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.

R 330.259 Statewide stroke registry.
Rule 9. (1) The purpose of the stroke registry is to collect and analyze system data to evaluate the delivery of stroke care, develop stroke risk reduction initiatives, and provide resources for stroke research and education.
(2) The department shall coordinate data collected by the stroke centers and EMS 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 330.258(1)(a) and the following:

(i) Definitions of what constitutes a reportable stroke 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 of stroke centers of the required registry data sets and to update the stroke centers and providers as necessary, when the registry data set changes.

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

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

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

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

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

R 330.260 Regional performance improvement.

Rule 10. (1) Each regional stroke system shall develop and implement a regional stroke care performance improvement program. This program must include the standards under R 330.254(1)(d) and R 330.257(5) and the development of an annual process for reporting to the department a review of all region-wide policies, procedures, and protocols.

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

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

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

(5) Each regional stroke 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, the data confidentiality provisions under the code, and any confidentiality provisions established by the RPSRO.

(6) The performance improvement process must include the standards under R 330.254(1)(d), and include all of the following system components to be evaluated:

(a) Components of the regional stroke care plan.

(b) Triage criteria and effectiveness.

(c) Stroke center diversion.

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

(7) Each regional stroke system is responsible for the ongoing evaluation of the stroke system of care. Accordingly, each region shall develop a procedure for receiving information from the regional stroke care system constituents on the implementation of various components of that region's stroke care system, and include the standards under R 330.254(1)(e), and include all the following:

(a) Components of the regional stroke care plan.

(b) Triage criteria, and effectiveness.

(c) Stroke center diversion.

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

(8) Based on 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, if needed. The report must be made available to all regional stroke system constituents.

(9) The region shall ensure that all stroke centers participate in this annual evaluation process and encourage all other hospitals that treat stroke patients to participate. 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.

R 330.261 Destination protocols.

Rule 11. Local MCAs shall develop and submit stroke 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 MCA shall formally adopt and implement the protocol. The following factors must be used in evaluating destination protocols:

(a) An evidence-based validated stroke assessment tool.

(b) Stroke patients shall not be transported to a healthcare facility that does not participate in the state stroke care system unless there is no other reasonable alternative available.

(c) Stroke patients shall be transported to the closest appropriate stroke center as identified in regional and local medical control protocols.

(d) If a level I, level II or level III stroke center is not within a reasonable distance from the incident scene, the stroke patient shall be transported to a level IV stroke center.

(e) Each region shall make appropriate determinations for stroke patient destination based on what is best for the patient.

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

R 330.262 Stroke patient inter-facility transfer protocols.

Rule 12. (1) All designated stroke centers shall maintain inter-facility transfer protocols for stroke patients that are consistent with regional and local medical control protocol and are compliant with 42 USC 1395dd.

(2) All level IV stroke centers shall develop and implement formal policies based on published guidelines for the transfer of stroke patients who need care at a level III, level II, or level I stroke center.

(3) All level III stroke centers shall develop and implement formal policies based on published guidelines for the transfer of stroke patients who need care at a level II or level I stroke center.

(4) All level II stroke centers shall develop and implement formal policies based on published guidelines for the transfer of stroke patients who need care at a level I stroke center.

(5) Stroke patients shall be transported to a hospital designated as a stroke center.

R 330.263 Criteria for transfer protocols; criteria.

Rule 13. (1) Designated stroke centers shall contact the department for current stroke patient transfer guidelines.

(2) Stroke care, including stroke bypass, must be provided to patients as necessary pursuant to 42 USC 1395dd or other applicable laws.