

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BUREAU OF EMS TRAUMA AND PREPAREDNESS

EMERGENCY MEDICAL SERVICES - LIFE SUPPORT AGENCIES AND
MEDICAL CONTROL

Filed with the secretary of state on May 19, 2023

These rules take effect 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, 20910, and 20975 of the public health code, 1978 PA 368, MCL 333.2233, 333.20910, and 333.20975, and Executive Reorganization Order No. 2015-1, MCL 400.227)

R 325.22101, R 325.22102, R 325.22103, R 325.22111, R 325.22112, R 325.22113, R 325.22114, R 325.22116, R 325.22117, R 325.22118, R 325.22120, R 325.22122, R 325.22123, R 325.22124, R 325.22125, R 325.22126, R 325.22127, R 325.22131, R 325.22132, R 325.22133, R 325.22134, R 325.22135, R 325.22136, R 325.22137, R 325.22138, R 325.22165, R 325.22181, R 325.22182, R 325.22183, R 325.22184, R 325.22186, R 325.22187, R 325.22189, R 325.22190, R 325.22191, R 325.22193, R 325.22194, R 325.22201, R 325.22202, R 325.22203, R 325.22204, R 325.22205, R 325.22206, R 325.22207, R 325.22208, R 325.22209, R 325.22210, R 325.22211, R 325.22212, R 325.22213, R 325.22214, R 325.22215, R 325.22216, and R 325.22217 of the Michigan Administrative Code are amended, and R 325.22139 and R 325.22218 are added, as follows:

PART 1. GENERAL PROVISIONS

R 325.22101 Definitions; A to D.

Rule 101. As used in these rules:

(a) "Accountable" means ensuring compliance on the part of each life support agency or emergency medical services personnel in carrying out emergency medical services based upon protocols established by the medical control authority and approved by the department.

(b) "Air ambulance service" means providing at least advanced life support services utilizing an air ambulance or ambulances that operate in conjunction with a base hospital or hospitals. Air ambulance service may also include any of the following:

- (i) Searches.
- (ii) Emergency transportation of any of the following:
 - (A) Drugs.
 - (B) Organs.
 - (C) Medical supplies.

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(D) Equipment.

(E) Personnel.

(c) "Back-up air ambulance" means an air ambulance that is used to provide air ambulance services if the primary air ambulance is not available to provide air ambulance services.

(d) "Board certified in emergency medicine" means current certification by the American Board of Emergency Medicine, the American Board of Osteopathic Emergency Medicine, or other organization approved by the department that meets the standards of these organizations.

(e) "Code" means the public health code, 1978 PA 368, MCL 333.1101 to 333.25211.

(f) "Designated event" means a temporary event, such as an air show, of no more than 7 days in duration that requires full-time, on-site availability of an air ambulance.

(g) "Direct communication" means a communication methodology that ensures medical control authority supervision of a life support agency when performing emergency medical services through any of the following methods:

(i) Direct interpersonal communications at the scene of the emergency.

(ii) Direct verbal communication by means of an approved two-way telecommunications system operating within the medcom requirements.

(iii) Protocols adopted by the medical control authority and approved by the department.

(iv) Other means approved by the department that are not in conflict with the medcom requirements.

(h) "Disciplinary action" means an action taken by the department against a medical control authority, a life support agency, or individual, or an action taken by a medical control authority against a life support agency or individual for failure to comply with the code, rules, or protocols approved by the department.

R 325.22102 Definitions; E to M.

Rule 102. As used in these rules:

(a) "Emergency medical services intercept" means an ambulance operation is transporting an emergency patient from the scene of an emergency, and requests patient care intervention from another transporting ambulance operation.

(b) "Emergency medical services telecommunications" means the reception and transmission of voice or data, or both, information in the emergency medical services system consistent with the medcom requirements prescribed by the department.

(c) "Field study status" means that process required under sections 20910 and 20956 of the code, MCL 333.20910 and 333.20956.

(d) "Fixed wing aircraft" means a non-rotary aircraft transport vehicle that is primarily used or available to provide patient transportation between health facilities and is capable of providing patient care according to orders issued by the patient's physician.

(e) "Ground ambulance" means a vehicle that complies with design and structural specifications, as that term is defined in these rules, and is licensed as an ambulance to provide transportation and basic life support, limited advanced life support, or advanced life support.

(f) "Hold itself out" means the agency advertises, announces, or charges specifically for providing emergency medical services, as that term is defined in the code.

(g) "License" means written authorization issued by the department to a life support

agency and its life support vehicles to provide emergency medical services, as that term is defined in the code.

(h) "License expiration date" means the date of expiration indicated on the license issued by the department.

(i) "Licensure action" means probation, suspension, limitation, or removal by the department of a license for a life support agency or a life support vehicle for violations of the code or these rules.

(j) "Life support agency" means an ambulance operation, non-transport pre-hospital life support operation, air transport operation, or medical first response service.

(k) "Life support vehicle" means an ambulance, a non-transport, prehospital life support vehicle, or a medical first response vehicle, as that term is defined in the code.

(l) "Medcom requirements" means medical communication requirements for an emergency medical services communication system.

(m) "Medical control" means supervising and coordinating emergency medical services through a medical control authority, as prescribed, adopted, and enforced through department-approved protocols, within an emergency medical services system.

(n) "Medical control authority" means an organization designated by the department to provide medical control.

(o) "Medical control authority area" means the geographic area composed of a county, group of counties, or parts of an individual county, as designated by the department.

(p) "Medical control authority board" means a board appointed by the participating organizations to carry out the responsibilities and functions of the medical control authority.

(q) "Mutual aid" means a written agreement between 2 or more licensed life support agencies for the provision of emergency medical services when an agency is unable to respond to a request for emergency services, or an agreement according to the direction of a medical control authority in accordance with department approved protocols.

R 325.22103 Definitions; P to S.

Rule 103. As used in these rules:

(a) "Physician" means a doctor of medicine or doctor of osteopathy who possesses a valid license to practice medicine in this state.

(b) "Primary dispatch service area" means a service area.

(c) "Professional standards review organization" means a committee established by a life support agency or a medical control authority for the purpose of improving the quality of medical care.

(d) "Protocol" means a patient care standard, standing orders, policy, or procedure for providing emergency medical services that is established by a medical control authority and approved by the department under section 20919 of the code, MCL 333.20919.

(e) "Quality improvement program" means actions taken by a life support agency, medical control authority, or jointly between a life support agency and medical control authority with a goal of continuous improvement of emergency medical services in accordance with section 20919 of the code, MCL 333.20919.

(f) "Regional trauma network" means an organized group comprised of the local medical control authorities within a region, which integrates into existing regional emergency preparedness, and is responsible for appointing a regional trauma advisory council and creating a regional trauma plan.

- (g) "Rotary aircraft" means a helicopter that is licensed under the code as an ambulance.
- (h) "Service area" means the geographic area in which a life support agency is licensed to provide emergency medical services for responding to an emergency.

PART 2. LIFE SUPPORT AGENCIES-GENERAL

R 325.22111 Life support agencies; general provisions.

Rule 111. (1) A life support agency shall not operate unless it is licensed by the department and operates under the direction of a medical control authority in accordance with department-approved protocols. A life support agency shall not operate at a level that exceeds its license or violates approved medical control authority protocols, unless otherwise allowed by part 209 of the code, MCL 333.20901 to 333.20979.

(2) A life support agency license shall do both the following:

(a) Communicate approved protocols to appropriate emergency medical services personnel.

(b) Provide emergency medical services in accordance with protocols established by the medical control authority and approved by the department.

(3) A life support agency application shall not be approved by the department unless signed by the medical director of each medical control authority responsible for the service area of the life support agency in accordance with R 325.22205(2). The medical director's signature serves as confirmation that the medical control authority intends to provide medical control to the life support agency.

(4) A life support agency, except an aircraft transport operation, shall provide at least 1 life support vehicle for response to requests for emergency assistance on a 24-hour-a-day, 7-day-a-week basis in accordance with its licensure level and medical control authority protocols.

(5) All life support agencies shall have a mutual aid agreement with another life support agency to ensure a response within the bounds of its service area.

(6) If no other life support agency is licensed in the medical control authority that meets this criteria, a mutual aid agreement may be entered into with a life support agency in an adjacent medical control authority. This does not preclude a life support agency from entering into additional mutual aid agreements with other life support agencies that are at a level of licensure that is less than their level of licensure.

(7) A life support agency shall notify the jurisdictional medical control authority of any of the following:

(a) Any investigations, disciplinary actions, or exclusions against the life support agency with the potential to impact service delivery.

(b) Action taken by an agency against emergency medical services personnel based on a violation of section 20958 of the code, MCL 333.20958.

R 325.22112 Patient destination; transporting agencies.

Rule 112. (1) An ambulance operation, both ground and rotary, shall transport an emergency patient only to an organized emergency department located in and operated by 1 of the following:

(a) A hospital licensed under part 215 of the code, MCL 333.21501 to 333.21571.

(b) A freestanding surgical outpatient facility licensed under part 208 of the code, MCL 333.20801 to 333.20821, that operates a service for treating emergency patients 24-hours-a-day, 7-days-a-week, and complies with medical control authority protocols.

(c) An off-campus emergency department of a hospital licensed under part 215 of the code, MCL 333.21501 to 333.21571, if the off-campus emergency department is available for treating emergency patients 24-hours-a-day, 7-days-a-week, complies with medical control authority protocols, and has obtained provider-based status under 42 CFR 413.65.

(2) An ambulance operation may transport to an alternate destination requested by the medical control authority and approved by the department under field study status.

R 325.22113 Patient transfers; ground, rotary, aircraft transport.

Rule 113. (1) A person shall not transport a patient by stretcher, cot, litter, or isolette unless it is done in a licensed ambulance or aircraft transport vehicle. The life support agency transporting the patient shall require that any applicable department-approved protocols of the medical control authority are followed in accordance with section 20921(4) and (5) of the code, MCL 333.20921.

(2) An out-of-state service that is coming to this state to transfer a patient from a Michigan facility to a facility in another state or country shall be licensed or certified within its own jurisdiction.

R 325.22114 Professional standards review organization: data collection.

Rule 114. Each life support agency shall establish a professional standards review organization for improving the quality of emergency medical services. As part of the professional standards review organization, each life support agency shall collect data to assess the need for and quality of emergency medical services. The data must be submitted to the medical control authority as determined by department-approved medical control authority protocol as required in R 325.22207.

R 325.22116 Inability to provide service.

Rule 116. (1) If a life support agency cannot operate or staff at least 1 vehicle for response to an emergency within its service area in accordance with the code, these rules, or applicable protocols, then the life support agency shall do all the following:

(a) Immediately notify the department and medical control authority within its service area if it cannot provide at least 1 life support vehicle available for response to requests for emergency assistance on a 24-hour-a-day, 7-day-a-week basis in accordance with medical control authority protocols. This rule excludes air ambulance services and aircraft transport operations when the weather does not meet weather minimums outlined by a national accrediting body for air ambulance services.

(b) Immediately notify the department of a change that would alter the information contained on its application.

(c) Notify the dispatch center that regularly receives requests for its services, and other public safety agencies if appropriate, that it is not available to respond. The notification must advise the dispatch center of the period in which the agency will be out of service and the name of the agency that will be covering its service area.

(d) Notify life support agencies providing mutual aid.

(2) The life support agency shall comply with R 325.22202(4).

R 325.22117 Maintenance of medical records.

Rule 117. In accordance with section 20175(1) of the code, MCL 333.20175, a life support agency shall maintain an accurate record of each case where care is rendered in a format approved by the medical control authority. Medical records must be maintained for a minimum of 7 years. However, records of minors must be maintained until they reach 25 years of age.

R 325.22118 Removal of vehicle from service; licensure; interagency vehicle transfer, lease, loan, from another life support agency.

Rule 118. (1) A life support agency shall notify the department if it permanently removes a vehicle from service. If a vehicle is permanently removed from service, then the agency shall contact the department, in writing, within 30 days after removal. The notification must include the make, model, year, and vehicle identification number on an application prescribed by the department. The agency shall remove all oscillating, rotating, or flashing lights, and words, phrases, signs, symbols, or insignia that advertise or convey to the public that it provides emergency medical services before transfer or sale of the vehicle.

(2) A life support vehicle license is nontransferable. A life support agency may temporarily use a state licensed life support vehicle of another licensed life support agency through a loan. Vehicle loans may occur if mechanical problems prevent an agency from deploying its existing vehicles. The life support agency acquiring the vehicle shall do all the following:

(a) Notify the department of the loan within 3 business days on an application prescribed by the department.

(b) Replace an existing licensed vehicle with the loaned vehicle at the agency. The loaned vehicle must not increase the total number of vehicles the agency is licensed to use.

(c) Use the loan for a maximum of 60 calendar days.

(d) Extend the loan 1 time for 60 additional calendar days if the agency notifies the department on an application prescribed by the department.

(3) A life support agency that obtains a vehicle through a gift, lease, transfer, or purchase from another life support agency shall comply with both of the following:

(a) Submit an application for the vehicle in accordance with R 325.22190.

(b) Comply with R 325.22181.

(4) A life support agency that gives, leases, transfers, or sells a vehicle to another life support agency shall comply with subrule (1) of this rule.

R 325.22120 Life support agencies licensed in other states or dominion of Canada.

Rule 120. (1) A life support agency licensed in another state or the dominion of Canada that responds to emergencies in this state shall be licensed by the department unless specific intergovernmental agreements exist between the department, the dominion of Canada, or the other state.

(2) A life support agency licensed in another state or in the dominion of Canada that responds to emergencies is accountable to the medical control authority in whose geographical boundaries initial patient contact is made.

R 325.22122 Misleading information concerning emergency response.

Rule 122. A life support agency shall not knowingly provide a person with false or

misleading information concerning the time at which an emergency is initiated or the location from which the response is being initiated. The department or medical control authority may investigate any allegation of wrongdoing submitted under this rule. If a violation of this rule occurs, the department or medical control authority may take any corrective action authorized under the code and these rules.

R 325.22123 Spontaneous use of vehicle under exceptional circumstances; written report.

Rule 123. (1) If an ambulance operation is unable to respond to an emergency patient within a reasonable time, a vehicle may be used under exceptional circumstances, as defined by department policy, to provide, without charge or fee and as a humane service, transportation for the emergency patient.

(2) Emergency medical personnel who transport, or who make the decision to transport, an emergency patient under subrule (1) of this rule shall file a written report with the medical control authority describing the incident within 7 days.

R 325.22124 Enforcement.

Rule 124. (1) The department may take any action authorized by sections 20162, 20165, and 20168 of the code, MCL 333.20162, 333.20165, and 333.20168, or other provisions of the code in response to a violation of the code or these rules. Enforcement actions include any of the following:

- (a) Denial, suspension, limitation, or revocation of a life support agency license.
- (b) The issuance of a nonrenewable conditional license effective for not more than 1 year.
- (c) The issuance of an administrative order to correct deficiencies and prescribing the actions the department determines necessary to obtain compliance with the code or to protect the public health, safety, and welfare.

(d) Imposition of an administrative fine.

(e) The issuance of an emergency order limiting, suspending, or revoking license.

(2) A life support agency that is granted a 1-year nonrenewable conditional license by the department shall comply with, at a minimum, all the following:

(a) Provide at least 1 vehicle for response to requests for emergency assistance on a 24-hour-a-day, 7-day-a-week basis in accordance with its licensure level.

(b) Submit a statement of the reasons for the life support agency's inability to comply with the code for licensure.

(c) Develop a plan of action to meet all licensure requirements. The plan must be submitted to the medical control authority and the department.

(d) Submit a monthly report to the medical control authority that outlines the progress made on the plan.

(e) Report all out-of-service time to each involved medical control authority.

(3) A life support agency that is granted a 1-year nonrenewable conditional license shall comply with all licensure fee requirements in the code.

R 325.22125 Life support agency; licensure at higher level of care; requirements.

Rule 125. (1) A life support agency seeking licensure at a higher level qualifies for that license only if the life support agency meets the following requirements:

(a) Under the code, a life support agency that is licensed to provide medical first response

life support may apply for licensure at the basic, limited advanced, or advanced life support level. A life support agency that is licensed to provide basic life support may apply for licensure at the limited advanced or advanced life support level. In the same manner, a life support agency that is licensed to provide limited advanced life support may apply for licensure at the advanced life support level.

(b) Each life support agency that meets the requirements of subdivision (a) of this subrule shall apply for a higher level of licensure on applications provided by the department and meet the requirements of the code and these rules. The application must include the required fee and identification of level of life support of the operation.

(2) A life support agency that obtains licensure at a higher level shall provide that level of care 24-hours-a-day, 7-days-a-week.

(3) If a life support agency applies to the department for licensure at a higher level than that of its current level, the department shall conduct an inspection of the agency and its vehicles. Verification of compliance with this subrule must be included with the application for licensure for each ground ambulance or non-transport, prehospital life support vehicle by both of the following methods:

(a) Provide, as part of the application, the name and address of the medical control authority or authorities under which the life support agency is operating. The agency shall complete an application for licensure, as prescribed by the department, for each medical control authority under which it operates. The signature on the application of the emergency medical services medical director, from each medical control authority, must verify that the medical control authority agrees to provide medical control to the life support agency.

(b) Attest, by signing the application, to all the following:

(i) The radio communication system for each ambulance or non-transport, prehospital life support vehicle complies with the medcom requirements.

(ii) Each vehicle meets minimum equipment requirements.

(iii) Minimum staff requirements are being met to operate at least 1 vehicle on a 24 hour-a-day, 7 day-a-week basis.

(iv) Each ground ambulance licensed by the department has a manufacturer certificate of compliance.

(4) Verification of compliance with this subrule must be available to the department upon request.

R 325.22126 Life support agency; medical control; disciplinary action.

Rule 126. (1) A medical control authority may exercise disciplinary action against a life support agency or its emergency medical services personnel that may result in the life support agency, or its personnel not being allowed to provide prehospital emergency care. The basis for these actions must be for noncompliance with protocols established by the medical control authority and approved by the department. Disciplinary action may include the suspension, limitation, or removal of medical control for the life support agency of a medical control authority providing medical control, from an individual providing emergency medical services care, or any other action authorized by the code.

(2) If a suspension or removal of medical control for a life support agency or individual occurs, the life support agency or individual shall not operate or practice in that medical control authority region until medical control is restored by the medical control authority.

(3) If a suspension or removal of medical control for a life support agency or individual occurs, the life support agency or individual may appeal the decision to the medical control authority. After appeals to the medical control authority have been exhausted, the life support agency or individual may appeal the medical control authority's decision to the statewide emergency medical services coordination committee. An appeal to the emergency medical services coordination committee must be filed with the department in writing not more than 30 calendar days following notification to the agency or individual of the final determination of the medical control authority.

(4) The emergency medical services coordination committee shall review the appeal of a life support agency or individual and make a recommendation to the department. The department shall consider the emergency medical services coordination committee recommendation and conduct its own review of the appeal. If the department determines that licensure action is required, the department shall provide a hearing in accordance with the code and chapter 4 of the administrative procedures act of 1969, 1969 PA 369, MCL 24.271 to 24.288.

R 325.22127 Life support agency; life support vehicle; inspection; contractor requirements.

Rule 127. (1) The department shall, at least annually, inspect or provide for the inspection of each life support agency. The department shall conduct random inspections of life support vehicles during the agency licensure period.

(2) A life support agency that receives accreditation from the Commission on Accreditation of Ambulance Services or another department-approved national accrediting organization as having equivalent expertise and competency in the accreditation of life support agencies, may not be subject to an agency inspection by the department if the life support agency meets both of the following requirements:

(a) Submits verification of accreditation described in this rule.

(b) Maintains accreditation as described in this rule.

(3) Accreditation of a life support agency does not prevent the department from conducting a life support agency inspection.

(4) Pursuant to section 20910(2)(b) of the code, MCL 333.20910, if emergency medical services activities apply to contracts with agencies or individuals for purposes of providing life support agency and life support vehicle inspections, the department shall notify each life support agency and medical control authority of the existence of the contracts, including the roles and responsibilities of those agencies or individuals having been awarded contracts.

PART 3. LIFE SUPPORT AGENCIES

R 325.22131 Life support agency; initial application.

Rule 131. A life support agency and its life support vehicles shall be licensed by the department in accordance with sections 20920, 20926, 20931, and 20941 of the code, MCL 333.20920, 333.20926, 333.20931, and 333.20941. The application for initial licensure must include all the following:

(a) Be on an application provided by the department and include the required fees and identification of level of life support of the agency.

(b) Specify each life support vehicle to be operated, the level of life support being provided by that life support vehicle, and include a certificate of insurance covering each life support vehicle as identified in this rule.

(c) Provide the name and address of each medical control authority under which the life support agency is operating. The agency shall complete an application for licensure, as prescribed by the department, for each medical control authority under which it operates. A signature on the application by the emergency medical services medical director, from each medical control authority, is proof that the medical control authority agrees to provide medical control to the life support agency.

(d) Provide an attestation, as evidenced by signing the application, of all the following:

(i) Radio communications for each life support vehicle comply with medcom requirements.

(ii) Each vehicle meets minimum equipment requirements.

(iii) Minimum staff requirements must be met to operate at least 1 vehicle on a 24 hour-a-day, 7 day-a-week basis, consistent with section 20921(3) and (4), 20927(3), 20932(2), or 20941(6) of the code, MCL 333.20921, 333.20927, 333.20932, and 333.20941, as appropriate.

(iv) A manufacturer certificate of compliance for each ground ambulance licensed by the department.

(e) Include evidence that the operation possesses not less than \$1,000,000.00 insurance coverage or is under a self-insurance program authorized under 1951 PA 35, MCL 124.1 to 124.13 for property damage and personal injury, except for rotary winged aircraft. An application for rotary winged aircraft must include evidence that the operation possesses not less than \$5,000,000.00 insurance coverage or is under a self-insurance program authorized under 1951 PA 35, MCL 124.1 to 124.13, for property damage and personal injury, except under section 20934(6) of the code, MCL 333.20934.

(f) Include full disclosure of the operation ownership, including all the following:

(i) Copies of documents relating to the official type of legal organization of the operation, stating whether it is an individual proprietorship, partnership, corporation, or subsidiary of another corporation or unit of government. These documents must be maintained by the operation and made available to the department upon request.

(ii) Copies of registration of the operation with the secretary of state or other designated official in each state that the agency is chartered, incorporated, or authorized to do business. These documents must be maintained by the operation and made available to the department upon request.

(iii) Disclose all legally responsible individuals, owners, or officers of the life support agency when submitting an application, including any trade names under which the organization operates. These must include, but are not limited to, the name or names by which the life support agency is known to the public.

(iv) Disclose all parent organizations and any person, as that term is defined in section 20908 of the code, MCL 333.20908, that have not less than a 10% interest in the life support agency.

(g) Identify 1 individual who will serve as the agency licensure administrator for the life support agency. The agency licensure administrator is the point of contact for licensing and inspection activities.

R 325.22132 Life support agency; operating requirements.

Rule 132. In addition to requirements prescribed in the code and these rules, life support agency shall do all the following:

(a) Establish and maintain a written procedure that explains the steps that will be followed when a complaint is received by the agency. This procedure shall be maintained by the agency and made available to the department upon request.

(b) Maintain evidence of participation in the county, local, or regional disaster plan. Approved protocols may be used to meet this requirement. These documents must be maintained by the operation and made available to the department upon request.

(c) Comply with medical record keeping requirements in accordance with R 325.22117.

(d) Maintain written policies and procedures that address safety and accident reduction and comply with all applicable state and federal health and safety laws as prescribed on the department-approved agency inspection form. These procedures must be maintained by the operation and be available to the department upon request.

(e) Require that each individual staffing a licensed life support agency complies with the code and applicable medical control authority protocols.

(f) Require that a life support vehicle is not operated while transporting a patient unless the ambulance is staffed in accordance with section 20921(3), (4), and (5) of the code, MCL 333.20921.

(g) Require that a non-transport prehospital life support vehicle is not operated unless it is staffed in accordance with sections 20927(3) and 20941(6) of the code, MCL 333.20927 and 333.20941.

(h) Require that an aircraft transport vehicle is not operated unless it is staffed in accordance with section 20932(2) of the code, MCL 333.20932.

(i) Maintain evidence of an orientation process of emergency medical services personnel that familiarizes them with the agency's policies and procedures and trains them in the use and application of all the equipment carried in the licensed life support vehicle. At a minimum, the orientation process must include an introduction to personnel duties and responsibilities, in addition to medical control authority protocols.

(j) Maintain access to the current version of all applicable protocols for each medical control authority under which the agency operates.

(k) Complete and submit patient care records according to department-approved medical control authority protocols.

(l) Participate in data collection and quality improvement activities authorized under medical control authority protocols.

(m) Ensure that each licensed life support vehicle meets all applicable vehicle standards and state minimum equipment requirements prescribed by the department and department-approved medical control authority protocols.

(n) Require compliance with medcom requirements.

(o) Not knowingly respond to, or advertise its services for, prehospital emergency patients from outside its service area except for mutual aid requests.

(p) Require that each individual operating a licensed ground life support vehicle during an emergency response or patient transport has completed a department-approved vehicle operation education and competency assessment.

R 325.22133 Life support agency; licensure requirements.

Rule 133. A life support agency shall comply with all the following:

- (a) Ensure compliance with the code and these rules.
- (b) Advise the department immediately of any changes that would alter the information contained on its licensure application, including any of the following:
 - (i) Change of ownership.
 - (ii) Change of facility name.
 - (iii) Change in vehicle status.
 - (iv) Change in agency licensure administrator contact information.
 - (v) Circumstances that preclude the life support agency from complying with staffing or minimum equipment requirements.
 - (vi) Change in communication ability to comply with medcom requirements.
 - (vii) Change in service area.
- (c) A life support agency shall require that an individual whose license is at least equal to the level of vehicle license is in the patient compartment when transporting an emergency patient, or consistent with department-approved medical control authority protocols.

R 325.22134 Additional licensure requirements for life support agencies approved to administer medications.

Rule 134. In addition to meeting the other licensure requirements of the code and these rules, a life support agency approved to administer medications by their local medical control authority shall do both of the following:

- (a) Comply with the procedures of drug acquisition, storage, security, dispensing, and accountability in accordance with department-approved medical control authority protocols and federal and state law.
- (b) If licensed at the limited advanced or advanced life support level, comply with the acquisition, storage, security, dispensing, and accountability procedures for intravenous solutions, tubing, and related apparatus in accordance with department-approved medical control authority protocols and in compliance with the federal and state law.

R 325.22135 Rotary aircraft ambulance operations; additional licensure requirements.

Rule 135. (1) In addition to meeting other licensure requirements of the code and these rules, an ambulance operation providing rotary aircraft transport shall do all the following:

- (a) Meet all equipment requirements of the Federal Aviation Administration for the specific type of aircraft and flying conditions under which the aircraft will operate as specified by the air taxi certificate of operation of the aircraft transport provider.
 - (b) Maintain accurate medical flight records concerning the transportation of each emergency patient in intrastate flights or interstate flights originating in this state. The records must be available to the department and the medical control authority of the originating scene, when requested.
 - (c) Meet department licensure requirements and follow department-approved medical control authority protocols when providing on-scene emergency care.
 - (d) Meet department licensure requirements when providing interfacility transfers.
 - (e) Provide verification of Medicaid participation. A new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation is provided to the department within 6 months after the new provider begins offering services.
- (2) An ambulance operation licensed in this state that provides rotary aircraft services or

fixed wing ambulance service shall be accredited by a department-approved national accrediting organization within 2 years after beginning operation. During the provisional period between licensing and accreditation, the air ambulance operation must provide all the following:

- (a) Written policies and procedures specifying the levels of patient care to be provided. The level of patient care provided must be commensurate with the education and experience of the staff and the capabilities of the base hospitals.
- (b) Written patient care protocols including provisions for continuity of care.
- (c) Written policies and procedures that define the roles and responsibilities of all staff members.
- (d) Written policies and procedures addressing the appropriate use of air ambulance services in accordance with section 20932a of the code, MCL 333.20932a.
- (e) A written communicable disease and infection control program.
- (f) A written plan for dealing with situations involving hazardous materials.
- (g) A planned and structured program for initial and continuing education and training, including didactic, clinical, and in-flight, for all scheduled staff members appropriate for the respective duties and responsibilities.
- (h) Written policies and procedures addressing the integration of the air ambulance service with public safety agencies governing the base hospitals including, but not limited to, the federal aviation administration, medical control authorities, life support vehicles and disaster planning.
- (i) A quality management program.
- (j) A clinical database for utilization review and professional standards review organization.
- (k) Procedures to screen patients to ensure appropriate utilization of the air ambulance service.

R 325.22136 Life support agency; issuance of license.

Rule 136. Receipt of the completed application by the department serves as attestation by the life support agency that the agency and life support vehicles being licensed comply with the minimum standards required by the department. Upon approval of the application, the department shall issue a license to the life support agency.

R 325.22137 Ambulance operation; false advertising; conflict of interest.

Rule 137. An ambulance operation may not do any of the following:

- (a) Induce or seek to induce any person engaging an ambulance to patronize a long-term care facility, mortuary, or hospital.
- (b) Advertise, or allow advertising of, within or on the premises of the ambulance operation or within or on an ambulance, the name or the services of an attorney, accident investigator, nurse, physician, long-term care facility, mortuary, or hospital. If 1 of those persons or facilities owns or operates an ambulance operation, then the person or facility may use its business name in the name of the ambulance operation and may display the name of the ambulance operation within or on the premises of the ambulance operation or within or on an ambulance.
- (c) Advertise or disseminate information for the purpose of obtaining contracts under a name other than the name of the person holding an ambulance operation license, the trade, or assumed name of the ambulance operation.
- (d) Use the terms "ambulance" or "ambulance operation" or a similar term to describe or

refer to the person unless the department licenses the person under section 20920 of the code, MCL 333.20920.

(e) Advertise or disseminate information leading the public to believe that the person provides an ambulance operation, unless that person does in fact provide that service and is licensed by the department.

R 325.22138 Life support agency; renewal.

Rule 138. (1) A life support agency shall complete an application for renewal and return the completed application to the department before the date of license expiration. Failure to receive a notice for renewal from the department does not relieve the licensee of the responsibility to apply for renewal.

(2) The license of a life support agency and its life support vehicles expire on the same date.

(3) An application for licensure renewal received by the department after the license expiration date, but within 60 calendar days after the expiration date requires the life support agency to comply with section 20936 of the code, MCL 333.20936.

(4) A life support agency may provide emergency medical services during the 60 days following its license expiration date, whether or not the department has received an application for renewal.

(5) An application for licensure renewal not received by the department within 60 calendar days after the license expires must be considered revoked.

(6) Reinstatement of the life support agency and life support vehicle licenses require completion of a new application for licensure, including all fees prescribed in section 20936 (1) and (2) of the code, MCL 333.20936.

R 325.22139 Aircraft transport operations; additional licensure requirements.

Rule 139. (1) In addition to meeting other licensure requirements of the code and these rules, an aircraft transport operation shall do all the following:

(a) Meet all equipment requirements of the Federal Aviation Administration for the specific type of aircraft and flying conditions under which the aircraft will operate, as specified by the air taxi certificate of operation of the aircraft transport provider.

(b) Maintain accurate medical flight records concerning the transportation of each emergency patient in intrastate flights or interstate flights originating in this state. The records must be available to the department and the medical control authority of the originating scene, when requested.

(c) Meet department licensure requirements when providing interfacility transfers.

(d) Provide verification of Medicaid participation. A new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation is provided to the department within 6 months after the new provider begins offering services.

(2) An aircraft transport operation licensed in this state shall be accredited by a department-approved national accrediting organization within 2 years of beginning operation. During the provisional period between licensing and accreditation, the aircraft transport operation shall provide all the following:

(a) Written policies and procedures specifying the levels of patient care to be provided. The level of patient care provided must be commensurate with the education and experience of the staff and the capabilities of the base hospitals.

(b) Written patient care protocols including provisions for continuity of care.

- (c) Written policies and procedures that define the roles and responsibilities of all staff members.
 - (d) Written policies and procedures addressing the appropriate use of aircraft transport in accordance with section 20932a of the code, MCL 333.20932a.
 - (e) A written communicable disease and infection control program.
 - (f) A written plan for dealing with situations involving hazardous materials.
 - (g) A planned and structured program for initial and continuing education and training, including didactic, clinical, and in-flight, for all scheduled staff members appropriate for the respective duties and responsibilities.
 - (h) Written policies and procedures addressing the integration of the air ambulance service with public safety agencies governing the base hospitals including, but not limited to, the Federal Aviation Administration, medical control authorities, life support vehicles and disaster planning.
 - (i) A quality management program.
 - (j) A clinical data base for utilization review and professional standards review organization.
 - (k) Procedures to screen patients to ensure appropriate utilization of the aircraft transport operation.
- (3) An air ambulance service may operate a back-up air ambulance if the primary air ambulance or ambulances are not available or for a designated event with prior notification and approval from the local medical control authority.
- (4) A back-up air ambulance must not be operated at the same time as the primary aircraft for the provision of air ambulance services except for a designated event or disaster.

PART 6. MEDICAL FIRST RESPONSE SERVICES

R 325.22165 Medical first response service; law enforcement; fire suppression agency.

Rule 165. (1) A medical first response service means a person licensed by the department to respond under medical control to an emergency scene with a medical first responder and equipment required by the department before the arrival of the ambulance. This includes a fire suppression agency only if it is dispatched for medical first response life support.

(2) A fire suppression agency shall be licensed as a life support agency, in accordance with R 325.22131, and provide life support as described in the code and these rules if it is dispatched to provide any care a medical first responder is qualified to provide under section 20906(8) of the code, MCL 333.20906.

(3) A law enforcement agency shall be licensed as a life support agency, in accordance with R 325.22131, and provide life support as described in the code and these rules if both of the following conditions are met:

- (a) Holds itself out as a medical first response service.
- (b) Is dispatched to provide medical first response life support.

(4) A law enforcement agency holds itself out as a medical first response service if it advertises or announces that it will provide patient care that may include any care a medical first responder is qualified to provide under section 20906(8) of the code, MCL 333.20906, or charges for those services.

PART 8. LIFE SUPPORT VEHICLES

R 325.22181 Ground ambulance; requirements.

Rule 181. (1) An ambulance operation shall maintain the manufacturer's certificate of compliance on file at the time of application to the department for licensure of each ground ambulance. The certificate of compliance must be executed by the final manufacturer of each ground ambulance and be on a form prescribed by the department.

(2) The manufacturer of a ground ambulance executing a certificate of compliance shall comply with the ambulance structural and mechanical specifications with 1 of the following standards that was in effect at the time of manufacture:

(a) Federal KKK-A-1822 standards, excluding the paint scheme.

(b) The Commission on Accreditation of Ambulance Services (CAAS) Ground Vehicle Standard for Ambulances (GVSA) in its entirety.

(c) The National Fire Protection Association (NFPA) 1917 Standard for Automotive Ambulances in its entirety.

(3) The manufacturer shall maintain test data demonstrating compliance.

(4) Once licensed for service, an ambulance must not be required to meet later modified state vehicle standards during its use by the ambulance operation that obtained the license.

(5) A ground ambulance referred to in subrule (2) of this rule must not be modified to alter its original design upon which the certificate of compliance was based unless a new certificate is issued verifying that the modifications have not altered the integrity of the vehicle.

(6) The patient compartment of a ground ambulance that has met applicable standards at the time of manufacture may be remounted on to a different chassis. The remounter may be a member of 1 or more of the following: Ford Qualified Vehicle Modifier, Mercedes Benz Sprinter Preferred Upfitter, Ram Q Pro Programs, or the National Truck Equipment Association Member Verification Program.

(7) A new manufacturer's certificate of compliance must be issued that identifies the new vehicle identification number and demonstrates compliance with either KKK, GVSA, or NFPA standards in accordance with subrule (2) of this rule.

R 325.22182 Non-qualifying vehicles for licensure.

Rule 182. (1) A ground ambulance that was originally manufactured before January 1, 1982, may not qualify for licensure by the department and must not be sold or donated in this state for use as a ground ambulance. This subrule does not apply to a ground ambulance that is currently licensed by the department and has been in continuous service before January 1, 1982.

(2) A ground ambulance manufactured after January 1, 1982, whose age from the date of manufacture exceeds 2 years, must have a safety inspection by a certified mechanic being sold to provide ground ambulance services. The inspection must be documented on a form developed by the department and include a notarized statement by the previous owner attesting that the ground ambulance has not been involved in a vehicular accident altering its safety. The documents required by this subrule must be submitted to the department by the purchaser as part of the application for licensure by the new owner.

R 325.22183 Life support vehicle sanitation.

Rule 183. A life support agency shall require that equipment, linen, and supplies be cleaned

or exchanged following each patient care use.

R 325.22184 Life support vehicles; displaying of name.

Rule 184. (1) A life support agency name shall be prominently displayed on the left and right side of all licensed life support vehicles.

(2) If the life support agency is operated by or advertised with a name different than the life support agency name, then the name may be displayed on the left and right side of the life support vehicle below the name of the life support agency. The advertised name shall be smaller than the life support agency name.

(3) A life support agency that identifies a level of licensure in its name or brand that is higher than the level of life support provided by a specific licensed vehicle, shall prominently display the actual level of licensure of the vehicle on the sides of the vehicle.

R 325.22186 Life support vehicles; patient care and safety equipment; review.

Rule 186. The department shall, with the advice of the emergency medical services coordination committee, annually review and modify, as necessary, the minimum equipment standards for life support vehicles.

R 325.22187 Rotary ambulance; requirements.

Rule 187. A rotary ambulance must meet all the following standards:

(a) Be capable of on-scene response and transportation of emergency patients.

(b) Be staffed in accordance with section 20921(3), (4), and (5) of the code, MCL

333.20921.

(c) Allow for patient access and treatment to the patient by the rotary ambulance personnel.

(d) Possess access that allows for safe loading and unloading of a patient without excessive maneuvering of the patient.

(e) Be temperature controlled for the comfort of the patient.

(f) Have adequate lighting for patient care and observation.

(g) Be equipped with communication capability with hospitals, life support vehicles, and medical control in accordance with the medcom requirements.

(h) Be capable of carrying a minimum of 1 patient in a horizontal position.

(i) Securely store equipment and make the equipment readily accessible.

(j) Operate under the medical control authority.

R 325.22189 Aircraft transport vehicle; requirements.

Rule 189. An aircraft transport vehicle must comply with all the following:

(a) Be authorized as part of a licensed aircraft transport operation.

(b) Be capable of carrying a minimum of 1 patient in a horizontal position.

(c) Provide a means of securing the litter while supporting a patient to the floor, walls, seats, specific litter rack, or any combination thereof.

(d) Ensure that the patient compartment has adequate lighting available for patient observation.

(e) Require that equipment is secured to the aircraft, readily accessible, and when not in use, securely stored.

(f) Ensure that the interior of each vehicle affords an adequate patient care and treatment area.

(g) Ensure that each vehicle is equipped with a cargo door or other entry that allows for loading and unloading of the patient without excessive maneuvering of the patient.

(h) Ensure that the interior of each vehicle is equipped with temperature control for the comfort of the patient.

R 325.22190 Life support vehicles; licensure and relicensure inspections; new and replacement vehicles; licensure at higher level of care.

Rule 190. Life support vehicles must be inspected as follows:

(a) The department may conduct random renewal inspections of life support vehicles, including medical first response vehicles. Inspections are unannounced unless circumstances warrant notifying a life support agency in advance that an inspection of its life support vehicles will be conducted. The department shall determine if prior notification of an inspection is warranted. A vehicle license may be renewed without an inspection.

(b) Submission of a licensure renewal application is considered an attestation by the life support agency that the vehicle meets all licensure requirements.

(c) A life support agency that is adding a new or higher licensure level for a life support vehicle shall submit an application, on forms provided by the department, and include the required fee. New and higher level of care vehicles must be inspected before being placed into service. Upon receipt of the application and required fee, the department shall inspect new or upgrade vehicles within 15 days after receipt of the application.

(d) A life support agency that is replacing a life support vehicle shall submit an application, on forms provided by the department, and include the required fee. A replacement vehicle means a life support agency has removed a vehicle from service and has replaced the vehicle with another.

(e) Replacement vehicles may be placed into service upon submission of an application and the required fee to the department. Upon receipt of the application and required fee, the department shall inspect the replacement vehicle within 15 days after receipt of the application.

(f) With written notification in a format specified by the department, a rotary ambulance back-up vehicle may be put into service for 30 days before it must comply with subdivisions (a) to (e) of this rule.

R 325.22191 Life support vehicles inspected; non-compliance; corrective measures.

Rule 191. If the department determines that a life support vehicle does not comply with the requirements of the code and these rules, then the following applies:

(a) If an agency has a vehicle determined to be noncompliant with minimum equipment items as identified on the inspection form, the agency has 24 hours to bring the vehicle into compliance and notify the department in writing of the corrections made. The vehicle may be returned to service before a reinspection with approval of the department. A reinspection must occur within 15 days after notification by the life support agency.

(b) If an agency fails to bring a vehicle into compliance within 24 hours, the agency shall remove the vehicle from service until the life support agency submits a written explanation of corrective action to the department and the department reinspects the vehicle. A vehicle taken out of service shall not function as an ambulance or life support vehicle until the vehicle passes the department reinspection.

(c) If a vehicle remains out of compliance for more than 15 calendar days from the date of

inspection, its license is automatically revoked. Reinstatement of the life support vehicle license requires reapplication for licensure, payment of the licensure fee prescribed in the code, and a reinspection of the vehicle.

(d) The department may immediately order a life support vehicle out of service if it determines that the health and welfare of a patient may be in jeopardy due to noncompliance with minimum equipment standards or defective and nonfunctional critical minimum equipment. A notice of that action be immediately provided to the life support agency by the department based upon the deficiencies found.

(e) A life support agency that takes corrective measures to bring a life support vehicle into compliance during the time of a department inspection will not receive notice of noncompliance. The inspection report must reflect that the corrective action and compliance have been met.

PART 9. COMMUNICATIONS REQUIREMENT

R 325.22193 Medcom requirements.

Rule 193. Medcom requirements must be reviewed annually and updated, if necessary, with the advice and recommendations of the emergency medical services coordination committee.

R 325.22194 Illegal interception of radio communications.

Rule 194. A person that receives any radio communication not intended for the general public may not use the contents of the communication for initiating an emergency medical service response as described in section 20963(2) of the code, MCL 333.20963.

PART 10. MEDICAL CONTROL AUTHORITY

R 325.22201 Medical control authorities; designation.

Rule 201. (1) The department shall designate a medical control authority to provide medical control for emergency medical services for a particular geographic area. The medical control authority shall operate in accordance with the code.

(2) A medical control authority shall be administered by the following:

(a) Each hospital licensed under part 215 of the code, MCL 333.21501 to 333.21571, that operates a service for treating emergency patients 24-hours-a-day, 7-days-a-week, may participate and serve on the medical control authority board in the ongoing planning and development activities of the medical control authority designated by the department.

(b) Each freestanding surgical outpatient facility licensed under part 208 of the code, MCL 333.20801 to 333.20821, that operates a service for treating emergency patients 24-hours-a-day, 7-days-a-week and meets standards established by the medical control authority may participate and serve on the medical control authority board in the ongoing planning and development activities of the medical control authority designated by the department. If a freestanding surgical outpatient facility participates in the medical control authority as described in this rule, the facility shall meet all applicable standards established by the medical control authority.

(3) Each hospital, off-campus emergency department with provider-based status, as described in R 325.22112(1)(c), and freestanding surgical outpatient facility shall comply with protocols

for providing services to a patient before care of the patient is transferred to hospital personnel.

R 325.22202 Medical control authorities; authority board; advisory body; medical director; responsibilities; approval.

Rule 202. (1) A medical control authority shall be approved by the department, and do all the following:

(a) Develop bylaws that define the medical control authority organizational structure.

(b) Appoint a medical control authority board to administer the medical control authority. The majority of the board shall be comprised, at a minimum, of members of the hospitals and, when applicable, freestanding surgical outpatient facilities and off-campus emergency department with provider-based status, as described in R 325.22112(1)(c). The board may include other entities as determined by the medical control authority bylaws.

(c) If the board also functions as the advisory body to the medical control authority as described in this rule, then the board shall include a representative of each type of life support agency and emergency medical services personnel functioning within the medical control authority's region.

(d) Appoint an advisory body, as that term is defined in section 20918(2) and (4) of the code, MCL 333.20918. The advisory body shall meet at least quarterly.

(e) Appoint a medical director, with the advice of the advisory body, in accordance with section 20918(3) of the code, MCL 333.20918. The medical director is responsible for medical control for the emergency medical services system served by the medical control authority. The medical control authority, with the advice of the advisory body, may appoint more than 1 physician to serve as medical director provided the individual meets all applicable criteria, or is approved by the department.

(f) Appoint a professional standards review organization to monitor and improve the quality of medical care.

(g) Hold each licensed life support agency and individual accountable to the medical control authority in the provision of emergency medical services, as that term is defined in department-approved protocols.

(h) Provide protocols for the practice of life support agencies and emergency medical services personnel as prescribed or approved by the department.

(i) Collect data as necessary to assess the quality and needs of emergency medical services throughout its medical control authority area.

(2) Each participating and nonparticipating hospital, off-campus emergency department with provider-based status, as described in R 325.22112(1)(c), and freestanding surgical outpatient facility within a medical control authority region shall follow all standards, policies, procedures, and protocols established by the medical control authority as approved by the department.

(3) Each medical control authority shall submit to the department current protocols for department review and approval. Department approval shall be on a 3-year cycle, or as defined by the department.

(4) The medical control authority shall notify the department if a life support agency is consistently unable to provide at least 1 life support vehicle 24-hours-a-day, 7-days-a-week.

R 325.22203 Medical control authority; denial, revocation, or suspension of designation.

Rule 203. (1) The department may deny, revoke, limit, or suspend designation of a medical

control authority upon finding that the medical control authority meets 1 or more of the following:

- (a) Is guilty of fraud or deceit in securing its medical control designation.
 - (b) Has failed to perform in accordance with the terms of its designation and its department-approved protocols.
 - (c) Has not maintained minimum criteria for medical control authorities, as established by the department.
 - (d) Has failed to develop protocols as identified in the code to protect the public health.
- (2) If the department denies, revokes, limits, or suspends a medical control authority designation, then the department shall designate a medical control authority to serve that medical control authority area.
- (3) The department shall provide notice of intent to deny, revoke, limit, or suspend medical control authority designation and provide for a hearing in accordance with the code and the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328.

R 325.22204 Medical control authority; advisory body.

Rule 204. A medical control authority shall appoint an advisory body, as that term is defined in section 20918(2) and (4) of the code, MCL 333.20918. The advisory body shall, at a minimum, do all the following:

- (a) Advise the medical control authority on the appointment of a medical director.
- (b) Advise the medical control authority on the development of protocols.
- (c) Meet at least quarterly.

R 325.22205 Medical control authority; medical director; responsibilities.

Rule 205. (1) The medical director is an agent of the medical control authority and is responsible for medical control for the emergency medical services system.

(2) The medical director shall ensure the provision of medical control. The medical director's signature on a life support agency's application for licensure or relicensure affirms that the medical control authority intends to provide medical control to the life support agency. If the medical director refuses to sign the life support agency application for licensure or relicensure, then the medical director shall notify the department in writing, within 5 business days, providing justification for denial based on a department-approved protocol. Refusal of a medical director to sign a life support agency application will result in denial justification review by the department.

- (3) The medical director shall do all the following:
- (a) Participate every 2 years in 1 department-approved educational program relating to medical control issues.
 - (b) Be responsible for the supervision, coordination, implementation, and compliance with protocols of the medical control authority.
 - (c) Receive input from, and be responsive to, the advisory body.

R 325.22206 Medical control authority; region.

Rule 206. (1) Not more than 1 medical control authority may be approved in each designated region.

(2) A medical control authority shall obtain approval from the department to change or combine medical control authority areas, or to assume a temporary contractual responsibility

for a portion of another medical control authority's region.

R 325.22207 Medical control authority; protocol development; promulgation of protocols; emergency protocol.

Rule 207. (1) Each medical control authority shall establish protocols, as that term is defined in section 20919 of the code, MCL 333.20919, which must include, but are not limited to all the following:

(a) The acts, tasks, or functions that may be performed by each level of emergency medical services personnel licensed under this part. Emergency medical services personnel shall not provide life support at a level that exceeds the life support agency license and approved medical control authority protocols.

(b) Procedures to ensure that life support agencies are providing clinical competency assessments to emergency medical services personnel before the individual provides emergency medical services within the medical control authority area.

(c) Medical protocols to require the appropriate dispatching of a life support agency based upon medical need and the capability of the emergency medical services system.

(d) A do-not-resuscitate protocol consistent with section 20919(1)(c) of the code, MCL 333.20919.

(e) A protocol consistent with part 56B of the code, MCL 333.5671 to 333.5685.

(f) Protocols defining the process, actions, and sanctions a medical control authority may use in holding life support agency or personnel accountable. This must include disciplinary action against a life support agency or emergency medical services personnel.

(g) Protocols defining the process to immediately remove medical control if the medical control authority determines that an immediate threat to the public health, safety, or welfare exists. These protocols must specify that a medical control authority has 3 business days to hold a hearing and make a determination.

(h) Protocols establishing that if medical control has been removed or suspended from a participant, that the participant shall not provide prehospital services in that until medical control is reinstated. If medical control is removed or suspended from a participant in the medical control authority, then the department and life support agency shall be notified within 1 business day of the removal. Medical control shall inform the department when medical control is reinstated.

(i) Protocols that ensure a quality improvement program as follows:

(i) The quality improvement program must include a requirement that each life support agency collects and submits data to the medical control authority.

(ii) Data must be reviewed by the medical control authority professional standards review organization.

(iii) Data must be protected in accordance with section 20919(1)(g) of the code, MCL 333.20919.

(j) Protocols that ensure an appeals process of a medical control decision is in effect.

(k) Protocols that specify that if life support agencies transport prehospital patients to hospitals outside of their originating medical control authority area, they will comply with their own medical control authority protocols.

(2) Each medical control authority shall develop standards for the withdrawal or restoration of a hospital or free-standing surgical outpatient facility, or off-campus emergency department with provider-based status, as described in R 325.22112(1)(c), to a medical control authority.

The protocol must include a provision to notify the regional trauma network of the withdrawal or restoration of a facility.

(3) Each medical control authority shall develop specific protocols applicable to the acquisition, storage, and use of drugs, intravenous fluids, and medical devices. Protocols must include all of the following:

(a) All drugs must be under the control of a pharmacist licensed in this state affiliated with a participating medical control authority hospital, free-standing surgical outpatient facility, or off-campus emergency department with provider-based status, as described in R 325.22112(1)(c).

(b) The medical control authority participating pharmacy shall provide medication and intravenous fluid exchange services in accordance with the protocols developed by the individual medical control authority and approved by the medical control authority medical control director and the department.

(c) In the instance of a recall relating to medical control authority participating pharmacy supplied medications or devices, the pharmacy shall notify the medical control authorities.

(d) All medication storage containers must be numbered. Each medication storage container must be inspected and inventoried by a medical control authority-approved pharmacy at least annually.

(e) All medication storage containers must have at least the following information affixed to the outside of the container:

(i) The name of the medical control approved pharmacy that most recently restocked the container.

(ii) The date of the most recent restock.

(iii) The name and date of the medications with the earliest expiration dates.

(iv) Notation of the licensed pharmacy personnel who completed and sealed the medication container.

(f) The medical control authority participating facility or agency in possession of intravenous fluids, tubing, and supplies shall have a method for verifying and tracking that the supplies are within their expiration date and do not have any active recall notices.

(g) The medication containers must be stored in a method that maintains the stability, integrity, and effectiveness of the medication contained therein.

(4) Emergency protocols developed in accordance with section 20919(3)(e) of the code, MCL 333.20919, must be submitted to the department, within 5 business days, for review and must remain in effect for not more than 60 days unless approved by the department.

R 325.22208 Medical control authority protocols; department review; approval; adoption by medical control authority.

Rule 208. (1) A medical control authority shall circulate, not less than 60 days before adoption, a draft of proposed protocols to all affected life support agencies within the emergency medical services system under the medical control authority.

(2) A medical control authority shall submit a written draft of proposed protocols to the department for review by the quality assurance task force no later than the tenth day of any given month. A protocol received not later than the tenth day of a given month must be reviewed that month. A protocol received after the tenth day of a given month must be reviewed the next month following the date of receipt by the department.

(3) The department shall consider any written comments received from persons within the

medical control authority when reviewing a protocol.

(4) The department shall provide written recommendations to the medical control authority within 60 days after receipt of a protocol in compliance with this rule, and comments, suggested changes, deletions, denial, or approval on the proposed protocol. Protocols resubmitted with changes or modifications by the medical control authority fall under the 60-day response deadline as prescribed in this rule.

(5) Following department approval of a protocol, the medical control authority may formally adopt the protocol.

R 325.22209 Medical control authority; additional standards.

Rule 209. A medical control authority may adopt protocols that require additional or more stringent standards for life support agencies, equipment, and personnel than those already required by the department to enhance its system. If a life support agency or emergency medical services personnel within the medical control authority disagree with the proposed protocol, the medical control authority shall provide the department with the medical and economic considerations such enhancements may have on the local community. The quality assurance task force shall review and make recommendations to the department before department approval.

R 325.22210 Medical control authority; life support agencies and personnel; compliance with protocols.

Rule 210. (1) A medical control authority shall establish written protocols for the process, actions, and sanctions a medical control authority may use in holding a life support agency or personnel accountable. These protocols must include disciplinary action against a life support agency or emergency medical services personnel to ensure compliance with all protocols or to protect the public health, safety, or welfare.

(2) A medical control authority may exercise disciplinary action against a life support agency and its emergency medical services personnel that may result in the life support agency, or its personnel not being allowed to provide emergency medical services. The basis for these actions must be for noncompliance with policies, procedures, or protocols established by the medical control authority. The disciplinary action may include the suspension, limitation, or removal of a life support agency or its personnel to provide emergency medical services within the medical control authority area.

(3) If disciplinary action against an agency or individual results in the suspension, limitation, or removal of medical control, the medical control authority shall advise the department, in writing, of the action within 1 business day.

(4) If a suspension or removal of medical control to a life support agency or individual occurs by the medical control authority, the life support agency or individual may not operate or practice in that medical control authority region until medical control is restored by the medical control authority.

(5) If a suspension or removal of medical control to a life support agency or individual occurs by the medical control authority, the life support agency or individual shall not operate or practice in that medical control authority area until medical control is restored by the medical control authority.

(6) In cases of malfeasance, misfeasance, or nonfeasance on the part of the medical control authority, the department shall take action to preserve medical control in a medical control

authority region.

R 325.22211 Medical control authority; quality improvement.

Rule 211. (1) A medical control authority shall establish a quality improvement protocol to ensure a quality improvement program is in place and functional.

(2) Data submitted by the life support agencies within the medical control authority area must be reviewed by the medical control authority professional standards review organization for the purpose of improving the quality of medical care within the medical control authority area.

R 325.22212 Medical control authority; appeals.

Rule 212. (1) A medical control authority shall incorporate procedures for the appeal of decisions made by the authority against a life support agency and emergency medical services personnel. Once appeals to the medical control authority have been exhausted, the decision made by the medical control authority may be appealed to the statewide emergency medical services coordination committee. An appeal to the emergency medical services coordination committee must be filed with the department in writing not more than 30 calendar days following notification to the agency or individual of the final determination of the medical control authority. The emergency medical services coordination committee shall issue an opinion on whether the actions or decisions of the medical control authority comply with the department-approved protocols of the medical control authority and the code.

(2) If a decision of the medical control authority is appealed to the emergency medical services coordination committee, the medical control authority shall document their decision to the statewide emergency medical services coordination committee for their review.

R 325.22213 Medical control authority; data collection; data confidentiality.

Rule 213. (1) A medical control authority shall collect data under the department-approved quality improvement protocol from each life support agency within the medical control authority area. Data collected must be reviewed by the medical control authority professional standards review organization to improve the quality of medical care within the medical control authority area and comply with section 20919(1)(g) of the code, MCL 333.20919. All data collected under section 20919(1)(g) of the code, MCL 333.20919, are confidential, not public record, not discoverable, and shall not be used as evidence in a civil action or administrative proceeding.

(2) A medical control authority shall submit data to the department as prescribed by the department and approved by the emergency medical services coordination committee.

(3) Medical control authorities shall have access to quality data residing within the Michigan Emergency Medical System Information System for incidents that occur within the medical control authority's geographic area.

R 325.22214 Medical control authority; special studies.

Rule 214. (1) A medical control authority that intends to establish a protocol involving skills, techniques, procedures, or equipment that is not included in this state's approved curriculum, may need to establish the practice as a special study. Determination that a proposed protocol is acceptable under current practice or requires a special study is decided by the quality assurance task force. A protocol may be approved as a medical control authority protocol under the following conditions:

- (a) The medical control authority provides documentation that the skill, technique, procedure, or equipment complies with 1 of the following:
- (i) The practice is recognized by a national organization as acceptable.
 - (ii) The practice has existing precedent in Emergency Medical System outside of this state.
 - (iii) There are published studies that support the safety and efficacy in its application of the practice within the emergency setting.
- (b) The medical authority provides the educational outline that will be implemented to instruct the emergency medical services personnel in the new skill, technique, procedure, or equipment, as well as the verification of competency that will be utilized.
- (c) A letter of support, justifying the need for the practice, signed by the medical director for the medical control authority participating in the practice implementation.
- (d) The medical control authority submits protocols that will be used for the practice.
- (e) The quality assurance task force may require data submission to this state for approval of the practice. If data is required for approval, the approval must be indicated as approval of the practice as a special study.
- (2) A medical control authority that intends to establish a protocol involving skills, techniques, procedures, or equipment that is not included in this state's approved curriculum, and is not consistent with its level of licensure requires a special study and must comply with all of the following:
- (a) Provide any available studies or supporting documentation indicating the practice has been studied. Published studies supporting the safety and efficacy of its applications within the emergency setting must also be submitted.
 - (b) The medical control authority provides an educational outline that will be implemented to instruct the emergency medical services personnel in the new skill, technique, procedure, or equipment, as well as the verification of competency that will be utilized and the plan for continued competency assurance, such as a continuing education plan.
 - (c) Provide a letter of support, justifying the need for the practice, signed by the medical director for the medical control authority participating in the special study.
 - (d) The medical control authority shall submit protocols that will be used for the practice.
 - (e) Identify life support agencies involved in the special study, their licensure level, the number of emergency medical services personnel to be trained, and their respective licensure levels.
 - (f) Submit a timeline indicating the proposed duration of the study.
 - (g) Describe the proposed data to be submitted to this state during the study. Generally, data submission is required quarterly.
 - (h) If the medical control authority designs the study to develop or contribute to generalizable knowledge, the medical control authority shall also submit documentation of Institutional Review Board approval, exemption, or not regulated status for the study.
- (3) A medical control authority that intends to establish a protocol involving skills, techniques, procedures, or equipment that is not included in this state's approved curriculum and is not consistent with either the level of licensure or scope of practice, involves human subject research under 45 CFR part 46, or intends to publish the human subject research, shall require a special study if it complies with all of the following:
- (a) Provide any available studies or supporting documentation indicating the practice has been studied. Published studies supporting the safety or efficacy of its application within the emergency setting must also be submitted.

(b) Submit initial and refresher education requirements and provide an educational outline to be implemented to instruct the emergency medical services personnel in the new skill, technique, procedure, or equipment, as well as verification of competency that will be utilized. Refresher education requirements must include frequency and content of refresher to maintain proficiency in skill, technique, procedure, or equipment.

(c) Identify life support agencies involved, their licensure level, the number of emergency medical services personnel to be trained, and their respective licensure levels.

(d) If providing mutual aid outside its medical control authority region, the medical control authority shall have a written agreement with another medical control authority to continue to utilize its protocols.

(e) Identify the quality review process that will be implemented.

(f) Submit protocols that will be included in the special study.

(g) Identify data parameters to be collected and the quality review process that will be implemented. The medical control authority shall submit quarterly reports, and upon completion of the study, submit a final report to the department.

(h) Obtain and submit an institutional review board approval or an institutional review board official exemption. If the medical control authority used a randomized study, include the consent form, method of institutional review board approval, and institutional review board approval letter.

(4) A special study may be terminated by the department, with the advice of the quality assurance task force, for any of the following reasons:

(a) The special study jeopardizes the health, safety, or welfare of the citizens of this state.

(b) There is evidence of failure to follow study parameters.

(c) There is evidence of failure to submit reports.

(d) The medical control authority or medical director requests termination.

(e) There is not sufficient data to support continuation.

(5) A special study may be considered complete when outcomes have been met, the timeline has been completed, or the study has been terminated by the department with the advice of the quality assurance task force. A final report must be submitted to the department by the medical control authority when the study is complete, unless the study is terminated by the department. The medical control authority may request any of the following for the protocol being studied:

(a) That it become a standard protocol for the requesting medical control authority.

(b) That it become a standard protocol for this state.

(c) That it be extended.

(d) That it be terminated.

(6) Disposition of the protocol is determined by the quality assurance task force.

R 325.22215 Medical control authority; communication requirements.

Rule 215. (1) A medical control authority shall comply with the ambulance-to-hospital radio communications system approval process, as prescribed by the medcom requirements.

(2) Each medical control authority shall designate an individual or organization to be responsible for maintaining records of the telecommunications activities in support of medical control. The records must be in the form of electronic recordings and maintained for 60 days.

(3) The department may add additional frequencies or other methods of communications to the medcom requirements. The department, before implementation, shall approve new requirements and technologies for ambulance-to-hospital communication.

R 325.22216 Medical control authority; interface with public safety agencies; authority for management of patient.

Rule 216. A medical control authority shall establish protocols that do all the following:

(a) Clarify that the authority for the management of a patient in an emergency is vested in the licensed health professional or licensed emergency medical services personnel at the scene of the emergency who has the most training specific to the provision of emergency medical care.

(b) Identify that when a life support agency is present at the scene of an emergency, authority for the management of an emergency patient in an emergency is vested in the physician responsible for medical control, until that physician relinquishes management of the patient to a licensed physician at the scene of an emergency.

(c) Specify that the appropriate public safety agency shall manage the scene of an emergency.

(d) Specify that if an emergency is declared, the declaration that an emergency no longer exists may be made only by an individual licensed under the code or a health professional licensed under the code who has training specific to the provision of emergency medical services in accordance with department-approved protocols.

R 325.22217 Medical control authority; interfacility transfers.

Rule 217. (1) A medical control authority may adopt a protocol that governs the transport of a patient from 1 health facility to another. If a medical control authority has not established department-approved protocols for the interfacility transport of a patient, then patient care must be determined according to written orders of the transferring physician within the scope of practice of the emergency medical services personnel.

(2) A life support agency is accountable to a medical control authority in which it has been approved to operate.

R 325.22218 Medical control authority; stretcher transport of nonemergency patients.

Rule 218. With department approval, a medical control authority may implement a protocol that governs the treatment and stretcher transport of nonemergency patients.