

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BUREAU OF EMS TRAUMA AND PREPAREDNESS

**EMERGENCY MEDICAL SERVICES - LIFE SUPPORT AGENCIES AND
MEDICAL CONTROL**

(By authority conferred on the director of the department of health and human services by section 20975 of 1978 PA 368, MCL 333. 20975, and section 2233 of 1978 PA 368, MCL 333.2233.)

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(s) that operates in conjunction with a base hospital(s). Other functions of the service may include searches, emergency transportation of drugs, organs, medical supplies, equipment, or personnel. An air ambulance service may operate a back-up air ambulance when the primary air ambulance(s) is not available or for a designated event with prior notification and approval from the local medical control authority.
- (c) "Back up air ambulance" means an air ambulance that is used to provide air ambulance services when the primary air ambulance is not available to provide air ambulance services. 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.
 - (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 MCL 333.1101 to MCL 333.25211 and known as the Michigan Public Health Code.
- (f) "Designated event" means a temporary event, such as an air show, of no more than seven (7) days in duration that requires the 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.

History: 2004 AACCS.

(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. Action may include suspension, limitation, or removal of medical control from a 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.

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R 325.22102 Definitions; E to O.

Rule 102. As used in these rules:

- (a) "Emergency medical services intercept" means a situation where 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 information in the emergency medical services system consistent with the medcom requirements prescribed by the department.
- (c) "Fixed wing aircraft" means a non-rotary aircraft transport vehicle.
- (d) "Ground ambulance" means a vehicle that complies with design and structural specifications, as 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.
- (e) "Hold itself out" means the agency advertises, announces, or charges specifically for providing emergency medical services as defined in the code.
- (f) "License" means written authorization issued by the department to a life support agency and its life support vehicles to provide emergency medical services as defined in the code.
- (g) "License expiration date" means the date of expiration indicated on the license issued by the department.
- (h) "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.
- (i) "Life support agency" means an ambulance operation, non-transport pre-hospital life support operation, air transport operation, or medical first response service.
- (j) "Life support vehicle" means an ambulance, a nontransport prehospital life support vehicle, aircraft transport vehicle, or a medical first response vehicle as defined in the code.
- (k) "Medcom requirements" means medical communication requirements for an emergency medical services communication system.
- (l) "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.
- (m) "Medical control authority" means an organization designated by the department to provide medical control.
- (n) "Medical control authority board" means a board appointed by the participating organizations to carry out the responsibilities and functions of the medical control authority.
- (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) "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.

History: 2004 AACCS.

R 325.22103 Definitions; P to T.

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 the 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 MCL 333.20919.
 - (e) "Quality improvement program" means actions taken by a life support agency, medical control authority, trauma facility, or jointly between a life support agency, medical control authority, or trauma facility, with a goal of continuous improvement of medical care in accordance with the code. Actions shall take place under a professional standards review organization, as provided in MCL 331.531 to 331.533.
 - (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.

History: 2004 AACCS.

R 325.22104 Terms in code.

Rule 104. Terms defined in the code have the same meanings when used in these rules.

History: 2004 AACCS.

PART 2. LIFE SUPPORT AGENCIES-GENERAL

R 325.22111 Life support agencies; general provisions.

Rule 111. (1) A life support agency must 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 must not operate at a level that exceeds its license or violates approved medical control authority protocols, unless otherwise allowed by Part 209 of the Public Health Code.

(2) The life support agency must:

(a) Be responsible for communicating 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 will 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 signature will serve as confirmation that the medical control authority intends to provide medical control to the life support agency.

(4) A life support agency, except a fixed wing aircraft transport operation, must provide at least 1 life support vehicle for response to requests for

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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 must have a mutual aid agreement with another life support agency in order to ensure a response within the bounds of its service area.

(6) A life support agency must 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 201958 of the code.

History: 2004 AACS.

R 325.22112 Patient destination; transporting agencies.

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

(a) A hospital licensed under part 215 of the code. ~~or to~~

(b) A freestanding surgical outpatient facility licensed under part 208 of the code 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, 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 special study status.

History: 2004 AACS; 2014 AACS.

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

Rule 113. (1) A person must 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 must 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.

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

History: 2004 AACS.

R 325.22114 Professional standards review organization; data collection.

Rule 114. Each life support agency may establish a professional standards review

organization for improving the quality of emergency medical services. As part of the organization, each life support agency must 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(1)(i).

History: 2004 AACCS.

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R 325.22115 Use of descriptive words, phrases, symbols, advertising.

Rule 115. A person must not use words, phrases, signs, symbols, or insignia that advertise or convey to the public that it provides emergency medical services or that it provides emergency medical services at a particular level unless it is licensed to do so.

History: 2004 AACCS.

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 must do all of the following:

(a) Immediately notify the department and medical control authority within its service area when 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 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 must comply with R 325.22202(4).

History: 2004 AACCS.

R 325.22117 Maintenance of medical records.

Rule 117. In accordance with section 333.20175 (1) of the Public Health Code, a life support agency must 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 7 years. However, records of minors shall be maintained until they reach 25 years of age.

History: 2004 AACCS.

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 must notify the department when it permanently removes a vehicle from service. If a vehicle is permanently

removed from service, the agency must contact the department, in writing, within 30 days of removal. Notification must include the make, model, year, and vehicle identification number on an application prescribed by the department. The agency must 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 must do all of 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 must comply with both of the following:

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

(b) Comply with R 325.22181.

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

History: 2004 AACCS.

R 325.22119 Operational routine vehicle and equipment inspection.

Rule 119. A life support agency must have a written policy in place to ensure vehicles and equipment are operational and provide documentation of not less than a weekly inspection program for all vehicles, communications equipment, and mechanical and electronic medical equipment.

History: 2004 AACCS.

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

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

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

History: 2004 AACCS.

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R 325.22121 Inquiry into ability to pay.

Rule 121. Life support agencies must not inquire about ability to pay or source of payment before providing life support consistent with its license and approved medical control authority protocols to each emergency patient.

History: 2004 AACS.

R 325.22122 Misleading information concerning emergency response.

Rule 122. A life support agency must not knowingly provide a person with false or misleading information concerning the time at which an emergency response will be 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.

History: 2004 AACS.

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, then a vehicle may be used under exceptional circumstances to provide, without charge or fee and as a humane service, transportation for the emergency patient. Emergency medical personnel who transport, or who make the decision to transport, an emergency patient must file a written report describing the incident with the medical control authority within 7 days.

History: 2004 AACS.

R 325.22124 Enforcement.

Rule 124. (1) The department may take any action authorized by sections 20162, 20165, 20168 of the code 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 to be necessary to obtain compliance with the code or to protect the public health, safety, and welfare.

(d) Impose 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 must comply with at least all of 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 must comply with all licensure fee requirements in the code.

History: 2004 AACCS.

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 must qualify for that license only if the life support agency meets the following requirements:

(a) Under the provisions of 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 must apply for a higher level of licensure on applications provided by the department and must meet the requirements of the code and these rules. Included with the application must be 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 must 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, then the department must conduct an inspection of the agency and its vehicles. Verification of compliance with this subrule must be included with the application for license for each ground ambulance or nontransport 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 must 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 that the radio communication system for each ambulance or nontransport prehospital life support vehicle complies with the medcom requirements, that each vehicle meets minimum equipment requirements, and that minimum staff requirements are being met in order to operate at least 1 vehicle on a 24 hour-a-day, 7 day-a-week basis. In addition, the agency must document that each ground ambulance licensed by the department has a manufacturer certificate of compliance. Verification of compliance with this subrule must be available to the department upon request.

History: 2004 AACCS.

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 and its emergency medical services personnel that may result in the life support agency or its personnel not being permitted 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 or its personnel to provide emergency medical services.

(2) If a suspension or removal of medical control for a life support agency or individual occurs, the life support agency or individual must 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 must review the appeal of a life support agency or individual and make a recommendation to the

department. The department will 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 must provide for a hearing in accordance with the code and the Administrative Procedures Act of 1969.

History: 2004 AACCS.

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

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

(2) A life support agency that receives accreditation from a department approved national accrediting organization 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, 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 must 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.

History: 2004 AACCS.

PART 3. LIFE SUPPORT AGENCIES

R 325.22131 Life support agency; initial application;

Rule 131. A life support agency and its life support vehicles must be licensed by the department in accordance with section 20920, 20926, 20931, and 20941 of the code. The application for initial licensure must include all of 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 subrule (f).

(c) Provide as part of the application, the name and address of each medical control authority under which the life support agency is operating. The agency must 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, will be proof that the medical control authority agrees to provide medical control to the life support agency.

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

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

(ii) Each vehicle meets minimum equipment requirements.

(iii) Minimum staff requirements will be met in order 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, as appropriate.

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

(e) Include evidence that the agency 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 et seq. for property damage and personal injury, except for rotary and fixed wing aircraft. An application for rotary and fixed wing aircraft must include evidence that the agency possesses not less than \$50,000,000.00 insurance coverage or is under a self-insurance program authorized under 1951 PA 35, MCL 124.1 et seq. for property damage and personal injury, except under 333.20934 (6) of the Public Health Code.

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

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

(ii) Copies of registration of the agency 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 agency and must be available to the department upon request.

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

(iv) Disclose all parent organizations and any person as defined in the code that have at least 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.

History: 2004 AACCS.

R 325.22132 Life support agency operating requirements.

Rule 132. In addition to requirements prescribed in the code and these rules, a life support agency must do all of 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 must be maintained by the agency and must be 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 agency and must be available to the department upon request.

(c) Comply with medical record keeping requirements in accordance with rule 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 agency and must be available to the department upon request.

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

(f) Require that an ambulance is not operated while transporting a patient unless the ambulance is staffed in accordance with section 20921(3)(4) and

(5) of the code.

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

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

(i) Maintain evidence of an orientation process of emergency medical services personnel that familiarizes them with the agency's policies and procedures and are trained in the use and application of all the equipment carried in the licensed life support vehicle. Included, at a minimum, must be 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 quality improvement activities authorized under department approved 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 as defined in these rules, 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.

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History: 2004 AACCS.

R 325.22133 Life support agency; licensure requirements.

Rule 133. A life support agency must comply with all of 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 which 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) An ambulance operation must 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.

History: 2004 AACCS.

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 must:

- (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 federal and state law.

History: 2004 AACCS.

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 must do all of 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 Michigan. 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 must certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services.

(2) An ambulance operation licensed in Michigan that provides rotary aircraft transport and utilizes a rotary aircraft from outside of Michigan to assist with intrastate transfers or mutual aid must assure that the secondary ambulance operation is licensed in the state of Michigan.

(3) An ambulance operation licensed in Michigan that provides rotary or fixed wing air ambulance service must be accredited by a department approved national accrediting organization within two years of beginning operation. During the provisional period between licensing and accreditation, the air ambulance operation must provide all of 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 333.20932 a;
- 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; and
- k. Procedures to screen patients to assure appropriate utilization of the air ambulance service.

History: 2004 AACCS.

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 are in compliance with the minimum standards required by the department. Upon approval of the application, the department must issue a license to the life support agency.

History: 2004 AACCS.

DRAFT

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

Rule 137. An ambulance operation shall 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 permit 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 or 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 under section 20920 of the code licenses the person.

(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.

History: 2004 AACCS.

R 325.22138 Life support agency; renewal.

Rule 138. (1) A life support agency must complete an application for renewal and must 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 will expire on the same date.

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

(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.

(5) An application for license renewal not received by the department within 60 calendar days following the date of license expiration will be considered revoked, effective on the sixty-first day.

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

History: 2004 AACCS.

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 **an** ambulance. This includes a fire suppression agency only if it is dispatched for medical first response life support.

(2) A fire suppression agency must 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.

(3) A law enforcement agency must 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) Be 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 or charges for those services.

History: 2004 AACCS.

PART 8. LIFE SUPPORT VEHICLES

R 325.22181 Ground ambulance; requirements.

Rule 181. (1) An ambulance operation must 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 must comply with the ambulance structural and mechanical specifications with one 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 must 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 one or more of the following: Ford Qualified Vehicle Modifier, Mercedes Benz Sprinter Preferred Upfitter, Ram Q Pro Programs and/or the National Truck Equipment Association Member Verification Program. 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.

History: 2004 AACCS; 2018 AACCS.

Editor's Note: An obvious error in R 325.221881 was corrected at the request of the promulgating agency, pursuant to Section 56 of 1969 PA 306, as amended by 2000 PA 262, MCL 24.256. The rule containing the error was published in *Michigan Register*, 2018 MR 22. The memorandum requesting the correction was published in *Michigan Register*, 2018 MR 23.

R 325.22182 Non-qualifying vehicles for licensure.

Rule 182. (1) A ground ambulance that was originally manufactured before January 1, 1982 will 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 will not apply to a ground ambulance that has been licensed and 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 must 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.

History: 2004 AACCS.

R 325.22183 Life support vehicle sanitation.

Rule 183. A life support agency must require that equipment, linen, and supplies must be cleaned or exchanged following each patient care use.

History: 2004 AACCS.

R 325.22184 Life support vehicles; displaying of name.

Rule 184. (1) A life support agency name must 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 must be smaller than the life support agency name.

(3) A life support agency which 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, will prominently display the actual level of licensure of the vehicle on the sides of the vehicle.

History: 2004 AACCS.

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

Rule 186. (1) The department must, with the advice of the emergency medical services coordination committee, annually review and modify, as necessary, the minimum equipment standards for life support vehicles.

History: 2004 AACCS.

R 325.22187 Rotary aircraft; requirements.

Rule 187. A rotary aircraft must meet all of 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.
- (c) Allow for patient access and treatment to the patient by the rotary aircraft 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 readily accessible.
- (j) Operate under a medical control authority.

History: 2004 AACCS.

History: 2004 AACCS.

R 325.22189 Fixed wing vehicle; requirements.

Rule 189. A fixed wing vehicle must comply with all of 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.

History: 2004 AACCS.

R 325.22190 Life support vehicles; licensure and renewal 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 will be unannounced unless circumstances warrant notifying a life support agency in advance that an inspection of its life support vehicles will be conducted. The department must 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 will be 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 must 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 must inspect new or upgrade vehicles within 15 calendar days of receipt of application.

(d) A life support agency that is replacing a life support vehicle must 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 must inspect the replacement vehicle within 15 calendar days of 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 has to comply with the above rules 325.22190 a-e.

History: 2004 AACCS.

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

Rule 191. If the department determines that a life support vehicle is not in compliance 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 will have 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 may occur within 15 calendar days of notification by the life support agency.

(b) If an agency fails to bring a vehicle into compliance within 24 hours, the agency must 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 must 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 will be automatically revoked. Reinstatement of the life support vehicle license will require 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 minimum equipment. A notice of such action shall 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.

History: 2004 AACCS.

PART 9. COMMUNICATIONS REQUIREMENTS

R 325.22192 Communications requirements; life support agencies.

Rule 192. A life support agency providing emergency medical services must use applicable communication systems consistent with its level of licensure in compliance with the code, these rules, and the medcom requirements as prescribed by the department.

History: 2004 AACCS.

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.

History: 2004 AACCS.

R 325.22194 Illegal interception of radio communications.

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

History: 2004 AACCS.

R 325.22195 Communications system application process; life support agencies; medical control authorities.

Rule 195. (1) A life support agency must comply with the ambulance-to- hospital radio communications system consistent with the medcom requirements in the medical control authorities in which they operate.

(2) A medical control authority shall comply with the ambulance-to- hospital radio communications system approval process, as prescribed by the medcom requirements, under any of the following conditions:

(a) A medical control authority upgrades to provide limited advanced or advanced life support oversight.

(b) An existing medical control authority changes the infrastructure of its communication system affecting ambulance-to-hospital communications.

(c) A change is made in an existing communications system that results in an inability of an agency or hospital to communicate with each other.

History: 2004 AACCS.

PART 10. MEDICAL CONTROL AUTHORITY

R 325.22201 Medical control authorities; designation.

(2) Rule 201. (1) The department must designate a medical control authority to provide medical control for emergency medical services for a particular geographic area. The Medical Control Authority must operate in accordance with code (PA 368 of 1978, as amended).

(2) A medical control authority must be administered by:

i. Each hospital licensed under part 215 of the code 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.

ii. Each freestanding surgical outpatient facility licensed under part 208 of the code 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 must meet all applicable standards established by the medical control authority.

iii. Each off-campus emergency department with provider based status as defined in R325.22112 (1) (c) licensed under part 215 of the code 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.

(3) Each hospital, off-campus emergency department with provider-based status as defined in R325.22112 (1) (c), and freestanding surgical outpatient facility must comply with protocols for providing services to a patient before care of the patient is transferred to hospital personnel.

History: 2004 AACCS.

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

Rule 202. (1) A medical control authority, as defined in the code, must be approved by the department and do all of the following:

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

(b) Appoint a medical control authority board, as defined in these rules, to administer the medical control authority. The majority of the board must 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 defined in R325.22112 (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 must include a representative of each type of life support agency and emergency medical services personnel functioning within the medical control authority's area.

(d) Appoint an advisory body as defined in section 20918 (2) and (4) of the code. The advisory body must 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. 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, as defined in these rules, for the purpose of monitoring and improving 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 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.

(j) Participate in the regional trauma networks comprised of collaborating local medical control authorities.

(2) Each participating and nonparticipating hospital, off-campus emergency department with provider-based status as defined in R325.22112 (1) (c), and freestanding surgical outpatient facility within a medical control authority area must follow all standards, policies, procedures and protocols established by the medical control authority as approved by the department.

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

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

DRAFT

History: 2004 MR 10, Eff. May 20, 2004.

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 or 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 must 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 shall provide for a hearing in accordance with the code and Chapter 4 of the Administrative Procedures Act of 1969 MCL 24271 et seq.

(4) The regional trauma network will be notified if a participating medical control authority designation has been denied, revoked, or suspended.

History: 2004 AACS.

R 325.22204 Medical control authority; advisory body.

Rule 204. A medical control authority must appoint an advisory body as defined in section 20918 (2) and (4) of the code. The advisory body must, at a minimum do all of 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.

History: 2004 AACS.

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 must 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 must 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 must do all of 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 of, and compliance with protocols of the medical control authority.

(c) Receive input from, and be responsive to, the advisory body.

History: 2004 AACCS.

R 325.22206 Medical control authority; area.

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

(2) A medical control authority must 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 area.

History: 2004 AACCS.

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

Rule 207. (1) Each medical control authority must establish protocols as defined in section 20919 of the code, which must include, but not be limited to all of the following:

(a) The acts, tasks, or functions that may be performed by each level of emergency medical services personnel licensed under this part.

i. Emergency medical services personnel must not provide life support at a level that exceeds the life support agency license and approved medical control authority protocols.

(b) Procedures to assure 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.

(e) A protocol consistent with MI POST PA 154 of 2017.

- (f) Protocols defining the process, actions, and sanctions a medical control authority may use in holding a 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 will not provide prehospital services in that medical control area until medical control is reinstated.
- i. If medical control is removed or suspended from a participant in the medical control authority, then the department and life support agency must be notified within 1 business day.
 - ii. Medical control must inform the department when medical control is reinstated.
- (i) Protocols that establish a quality improvement program.
- 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.
- (j) Protocols that establish an appeals process of a medical control authority decision.
- (k) Protocols that specify that if life support agencies transport prehospital patients to hospitals outside of their originating medical control authority region, they will comply with their own medical control authority protocols.
- (1)
 - (2) Each medical control authority must develop protocols for the withdrawal or restoration of a hospital, free standing surgical outpatient facility, or off-campus emergency department with provider-based status as defined in R325.22112 (1) (c) from a medical control authority or the restoration of a hospital, free standing surgical outpatient facility, or off-campus emergency department with provider-based status as defined in R325.22112 (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 must develop specific protocols applicable to the acquisition, storage, security, and use and exchange of drugs, intravenous fluids and medical devices.
 - 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 defined in R325.2212(1)(c).
 - b. The medical control authority participating pharmacy must 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 must 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 soonest 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 must 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 will maintain the stability, integrity, and effectiveness of the medication contained therein.
- (d)
- (4) Emergency protocols developed in accordance with section 20919 (3) (e) of the code 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.

History: 2004 AACCS.

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

Rule 208. (1) A medical control authority must circulate, at least 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 must submit a written draft of proposed protocols to the department for review by the quality assurance task force not later than the tenth day of any given month. A protocol received not later than the tenth day of a given month will be reviewed that month. A protocol received after the tenth day of a given month will be reviewed the next month following the date of receipt by the department.

(3) The department must consider any written comments received from persons within the medical control authority when reviewing a protocol.

(4) The department must provide written recommendations to the medical control authority within 60 days of 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 proposed protocol, the medical control authority may formally implement the protocol.

History: 2004 AACCS.

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 and sustain its system. If a life support agency or emergency medical services personnel within the medical control authority disagree with the proposed protocol, then the medical control authority must provide the department with the

medical and economic considerations such enhancements may have on the local community. The quality assurance task force must review and make recommendations to the department before department approval.

History: 2004 AACCS.

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

- (1) Rule 210. A medical control authority must establish written protocols defining 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 assure 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 emergency medical services personnel that may result in the life support agency and personnel not being permitted to provide emergency medical services. The basis for these actions must be for noncompliance with protocols established by the medical control authority. Such 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 must advise the department, in writing, of such action within one 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 must not operate or practice in that medical control authority region until medical control is restored by the medical control authority.

(5) In cases of malfeasance, misfeasance, or nonfeasance on the part of the medical control authority, the department must take action to preserve medical control in a medical control authority area.

History: 2004 AACCS.

R 325.22211 Medical control authority; quality improvement.

Rule 211. (1) A medical control authority must 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.

History: 2004 AACCS.

R 325.22212 Medical control authority; appeals.

Rule 212. (1) A medical control authority must implement protocols 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 must issue an opinion on whether the actions or decisions of the medical control authority are in accordance 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, then the medical control authority must document their decision to the statewide emergency medical services coordination committee for their review.

History: 2004 AACCS.

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

Rule 213. (1) A medical control authority must 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 must comply with section 20919(1)(g) of the code. All data collected under this section of the code are confidential, not public

record, not discoverable, and must not be used as evidence in a civil action or administrative proceeding.

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

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

History: 2004 AACCS.

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 are not included in the state 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 one of the following:

(i) The practice is recognized by a national organization as acceptable.

(ii) The practice has existing precedent in EMS outside of the state.

(iii) The practice has been studied and the published studies support the safety and efficacy in its application within the emergency setting.

(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.

(c) A letter of support, justifying the need for the practice, signed by the medical director for the medical control authority that will be 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 the state for approval of the practice. If data is required for approval, the approval will 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 are not included in this state or national approved curriculum, or is not consistent with level of licensure or scope of practice must require a special study and 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 should 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, i.e. CE plan.

- (c) A letter of support, justifying the need for the practice, signed by the medical director for the medical control authority that will be participating in the special study.
- (d) The medical control authority submits 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.

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- (f) Submit a timeline indicating the proposed duration of the study.
 - (g) Describe the proposed data to be submitted to the state for the duration of the study. Generally, data submission will be required quarterly.
 - (h) If the medical control authority intends to publish the results of the study, they must also submit Institutional Review Board approval or the letter of exemption status for the study.
- (3) A medical control authority that intends to establish a protocol involving skills, techniques, procedures, or equipment that are not included in the state or national approved curriculum, and is not consistent with the level of licensure or scope of practice, involves human subject research (CFR Title 45, Part 46) and/or intends the human subject research to be published must require a special study and 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 or efficacy of its application within the emergency setting should also be submitted.
 - (b) Submit initial and refresher education requirements. Provide 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 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) A letter of support, justifying the need for the practice, signed by the medical director for the medical control authority that will be participating in the special study.
 - (d) Submit a timeline indicating the duration of the study. The timeline must include the number of cases to reach conclusion of the study with an estimated date to reach requirement. The timeline may also be indicated as a duration only.
 - (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) If providing mutual aid outside its medical control authority area, the medical control authority must have a written agreement with another medical control authority to continue to utilize its protocols.
 - (g) Identify a special study coordinator.
 - (h) Identify data parameters to be collected and the quality review process that will be implemented. The medical control authority must submit quarterly reports, and upon completion of the study, submit a final report to the department.
 - (i) Submit protocols that will be included in the special study.
 - (j) Obtain and submit an institutional review board approval or an institutional review board official exemption. If 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) Become a standard protocol for the requesting medical control authority.

(b) Become a standard protocol for the state.

(c) Be extended.

(d) Be terminated.

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

History: 2004 AACCS.

R 325.22215 Medical control authority; communication requirements.

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

(2) Each medical control authority must 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 must be kept for 60 days.

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

History: 2004 AACCS.

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

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

(a) Clarify 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 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 must manage the scene of an emergency.

(d) Specify if an emergency is declared, the declaration that an emergency no longer exists must 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.

History: 2004 AACCS.

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 one 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 must be accountable as defined in these rules to a medical control authority in which it has been approved to operate.

History: 2004 AACCS.

R325.22218 Medical control authority; stretcher transport of nonemergency patients.

Rule 218. (1) With department approval, a medical control authority may implement a protocol which governs the treatment and stretcher transport of nonemergency patients.

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