Michigan Office of Administrative Hearings and Rules

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AGENCY REPORT TO THE JOINT COMMITEE ON ADMNINISTRATIVE RULES (JCAR)

1. Agency Information

Agency name:
Health and Human Services

Division/Bureau/Office:
Public Health Administration

Name of person completing this form:
Talisa Gauthier

Phone number of person completing this form:
517-241-0048

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gauthiert1@michigan.gov

Name of Department Regulatory Affairs Officer reviewing this form:
Mary Brennan

2. Rule Set Information

MOAHR assigned rule set number:
2022-20 HS

Title of proposed rule set:
EMS Life Support Agencies and Medical Control

3. Purpose for the proposed rules and background:

The rules address the licensing requirements for emergency medical services (EMS) life support agencies and medical control authorities (MCA). Since the introduction of these rules in 2004, there has not been a complete review of the rules to keep up with the changes that have occurred within the EMS system since that time. There were redundancies in some of the rules and other advances in evidence-based EMS practice that have been implemented as a result of the previous rules set that needed additional clarification or modifications, for example the changes in technology that have occurred since 2004. The last change to this rule set was in 2018 and it was R 325.22181. In addition, the Certificate of Need for air ambulance services Section 22215 of Act No. 368 of the Public acts of 1978 as amended and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, MCL 333.22215, 24.207 and 24.208 are being discontinued due to the Airline Deregulation Act. There is no longer the requirement for the Certificate of Need for air ambulances. However, this necessitates ensuring that appropriate portions of those statutes that address medical care requirements for air ambulances are contained in these proposed rules.

4. Summary of proposed rules:

The general purpose of the EMS Life Support Agencies and Medical Control addresses the licensing requirements for EMS life support agencies and medical control authorities in the advances in evidence-based EMS practice that have been implemented and ensuring that appropriate portions of the Certificate of Need that address medical care requirements for air ambulances are contained in the rules.

5. List names of newspapers in which the notice of public hearing was published and publication dates:

Battle Creek Enquirer, July 25, 2022; Oakland Press, July 27, 2022; Marquette Mining Journal, July 26, 2022.

6. Date of publication of rules and notice of public hearing in Michigan Register:

8/1/2022

7. Date, time, and location of public hearing:

8/15/2022 09:00 AM at JAR Conference Room , 1001 Terminal Road Lansing, Michigan 48909

8. Provide the link the agency used to post the regulatory impact statement and cost-benefit analysis on its website:

https://ARS.apps.lara.state.mi.us/Transaction/RFRTransaction?TransactionID=1379

9. List of the name and title of agency representative(s) who attended the public hearing:

Sabrina Kerr, EMS Section Manager, Bureau of EMS, Trauma, and Preparedness

10. Persons submitting comments of support:

None - suggestions only.

11. Persons submitting comments of opposition:

None - suggestions only.

12. Persons submitting other comments:

Robert Dunne, MD, FACEP, Medical Director for Detroit East MCA (DEMCA). Robert Olkowski, EMT-P IC, Assistant Chief, Detroit Fire Department-EMS

13. Identify any changes made to the proposed rules based on comments received during the public comment period:

	Name & Organization	Comments made at public hearing	Written Comments	Agency Rationale for Rule Change and Description of Change(s) Made	Rule number & citation changed
1	Robert Olkowski, EMT -P IC, Assistant Chief, Detroit Fire Department-EMS		Language needs to be consistent throughout the document. In several instances ambulance operation is used even though life support agency is the new terminology.	DHHS partially agrees/opposes this comment. There were some instances in this rule set where "ambulance operation" should have been "life support agency". Those have been identified and changed.	R 325.22116 R 325.22133 R 325.22136 R 325.22183
2	Robert Olkowski		If I am reading this right it means the state may override the MCA and allow an agency to be licenses even if they do not meet a MCA requirements. Should be changed to will not.	DHHS agrees with this comment. This should say "shall" instead of "may".	R 325.22111 (3)
3	Robert Olkowski		Needs to specify the same MCA. According to what I read as long as I have a MA agreement with any licensed agency I am good.	Subrule 6 has been rewritten with an additional subrule 7 added to end confusion.	R 325.22111 (6) R 325.22111 (7)
4	Robert Olkowski		Once again should be will not	DHHS agrees. "Shall" placed back in document.	R 325.22113 (1)

5	Robert Olkowski		“A minimum of…”	DHHS agrees. "a minimum of" added to the rule for those entities keeping files longer.	R 325.22117
6	Robert Olkowski		Define	DHHS has added language that the "exceptional circumstances" shall be defined in policy.	R 325.22123 (1)
7	Robert Olkowski		/or; /and	DHHS has changed "add" to "or" in the first sentence and is keeping "or" in the same sentence for this subrule.	R 325.22126 (1)
8	Robert Dunne, MD, FACEP, Medical Director for Detroit East MCA (DEMCA)		As far as removing the IRB section on pg 29, with the addition of section H, it looks like they are trying to exempt nonpublished special studies from IRB requirements such as unpublished QA/QI or investigation of a new established intervention outside of research. It is a bit weird that publishing or not is the standard for IRB approval or not- in general the standard for IRB approval is	DHHS agrees. After reviewing the language with DHHS Institutional Review Board staff, the language in subrules (2) and (3) now read as follows: (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	R 325.22214

				whether or not human subject research is taking place. This could be modified to "If the study amounts to human subjects research as defined by the common rule, Institutional Review Board approval or the letter of exemption status shall be submitted for the study."	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, it must 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 the human subject research to be published, must require a special study if it complies with all 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.	

14.Date report completed:

4/5/2023