

Michigan Office of Administrative Hearings and Rules

Administrative Rules Division (ARD)

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**REGULATORY IMPACT STATEMENT
and COST-BENEFIT ANALYSIS (RIS)**

Agency Information:

Department name:

Health and Human Services

Bureau name:

Public Health Administration

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Rule Set Information:

ARD assigned rule set number:

2022-20 HS

Title of proposed rule set:

EMS Life Support Agencies and Medical Control

Comparison of Rule(s) to Federal/State/Association Standard

1. Compare the proposed rules to parallel federal rules or standards set by a state or national licensing agency or accreditation association, if any exist.

Comparisons were made with standards from Commission on Accreditation of Medical Transport Systems (CAMTS), Commission on Accreditation of Ambulance Services (CAAS), National Accreditation Alliance Medical Transport Applications (NAAMTA), Guidelines for the Use and Availability of Helicopter Emergency Medical Transport by the U.S. Department of Transportation, and NHTSA for consistency in standards for EMS agencies and vehicles.

A. Are these rules required by state law or federal mandate?

Yes, these rules are required by section 20910 of 1978 PA 368, MCL 333.20910.

B. If these rules exceed a federal standard, please identify the federal standard or citation, describe why it is necessary that the proposed rules exceed the federal standard or law, and specify the costs and benefits arising out of the deviation.

These rules do not exceed any federal standard.

2. Compare the proposed rules to standards in similarly situated states, based on geographic location, topography, natural resources, commonalities, or economic similarities.

The proposed rules do not exceed standards in similarly situated states or federal standards, nor do they exceed standards from states within the Great Lakes State Council of the National Association of State EMS Officials (NASEMSO), which includes Ohio, Indiana, Illinois, Wisconsin, and Minnesota.

A. If the rules exceed standards in those states, please explain why and specify the costs and benefits arising out of the deviation.

The rules do not exceed standards in those states.

3. Identify any laws, rules, and other legal requirements that may duplicate, overlap, or conflict with the proposed rules.

Currently, the Air Ambulance Operations duplicates rules from the Certificate of Need. 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 are bills in the current legislative session to amend the Certificate of Need. This necessitates ensuring that appropriate portions of the Certificate of Need that address medical care requirements for air ambulances are contained in the EMS rules.

A. Explain how the rules have been coordinated, to the extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter. This section should include a discussion of the efforts undertaken by the agency to avoid or minimize duplication.

Meetings were held with the Certificate of Need State Officials and Air Medical groups to coordinate the transition from Certificate of Need to ambulance operation rules. The discussions of the efforts dealt with the comparison of both rule sets, and the necessary rule amendments in this set that would complement, not conflict, with the Certificate of Need rules.

4. If MCL 24.232(8) applies and the proposed rules are more stringent than the applicable federally mandated standard, provide a statement of specific facts that establish the clear and convincing need to adopt the more stringent rules.

MCL 24.232(8) does not apply to the proposed rules.

5. If MCL 24.232(9) applies and the proposed rules are more stringent than the applicable federal standard, provide either the Michigan statute that specifically authorizes the more stringent rules OR a statement of the specific facts that establish the clear and convincing need to adopt the more stringent rules.

MCL 24.232(9) does not apply to the proposed rules.

Purpose and Objectives of the Rule(s)

6. Identify the behavior and frequency of behavior that the proposed rules are designed to alter.

The proposed rules are meant to: streamline the new and annual licensing processes for all 830 life support agencies and the thousands of life support vehicles; improve the ability of reporting and tracking of licensing and compliance activities to ensure consistency and follow through; and improve patient safety through increased reporting and investigating identified issues with system, agency, and other public health concerns.

A. Estimate the change in the frequency of the targeted behavior expected from the proposed rules.

MDHHS is currently receiving approximately 300 complaints per year and it is anticipated that this number will increase due to ease of reporting and clarifying rules for personnel, medical control authorities, and agencies.

B. Describe the difference between current behavior/practice and desired behavior/practice.

Currently, notification of complaints are received on a reactive basis when departmental licensing action is needed. The desired practice would be notification when remediation is still possible.

C. What is the desired outcome?

The desired outcome is consistent and high quality patient care throughout the state of Michigan.

7. Identify the harm resulting from the behavior that the proposed rules are designed to alter and the likelihood that the harm will occur in the absence of the rule.

Without clear and consistent rules to define behavior and standards for EMS agencies, vehicles, and medical control authorities, the public, patients, and EMS personnel are at risk for serious harm, up to and including death. There are 59 medical control authorities that provide medical oversight to all EMS agencies, vehicles, and personnel. Without standards of care, there would be no consistency or assurance that patients are receiving quality care.

A. What is the rationale for changing the rules instead of leaving them as currently written?

The current rules are outdated, redundant, and there is language that is not clear, which results in confusion over roles and responsibilities for EMS agencies and medical control authorities. In addition, the medical quality component needed to be included in the rules due to the Certificate of Need being eliminated for air ambulances.

8. Describe how the proposed rules protect the health, safety, and welfare of Michigan citizens while promoting a regulatory environment in Michigan that is the least burdensome alternative for those required to comply.

There are no fee increases or new unfunded mandates to EMS agencies or medical control authorities. The proposed rule changes are designed to clarify and eliminate redundancies in order to protect the health, safety, and welfare of Michigan citizens.

9. Describe any rules in the affected rule set that are obsolete or unnecessary and can be rescinded.

No rules were selected for rescission for this rule promulgation.

Fiscal Impact on the Agency

Fiscal impact is an increase or decrease in expenditures from the current level of expenditures, i.e. hiring additional staff, higher contract costs, programming costs, changes in reimbursements rates, etc. over and above what is currently expended for that function. It does not include more intangible costs for benefits, such as opportunity costs, the value of time saved or lost, etc., unless those issues result in a measurable impact on expenditures.

10. Please provide the fiscal impact on the agency (an estimate of the cost of rule imposition or potential savings for the agency promulgating the rule).

There will be no fiscal impact on MDHHS as a result of promulgating these rules.

11. Describe whether or not an agency appropriation has been made or a funding source provided for any expenditures associated with the proposed rules.

No agency appropriation has been made nor a funding source provided for any expenditures associated with these rules.

12. Describe how the proposed rules are necessary and suitable to accomplish their purpose, in relationship to the burden(s) the rules place on individuals. Burdens may include fiscal or administrative burdens, or duplicative acts.

Rule 115 - there is a potential minimum cost to four EMS agencies that may need to adjust the lettering on their ambulances to reflect the actual level of service that the EMS agency provides. This is not a new requirement or burden on agencies, however, there was confusion on the interpretation of the rule, so changes were made to clarify. The rules are necessary for public safety and proper medical response, which outweighs the EMS agencies' burden in complying with the rules.

A. Despite the identified burden(s), identify how the requirements in the rules are still needed and reasonable compared to the burdens.

The requirement to show the actual level of service on the EMS agency vehicle is necessary so that the public knows what level of service they can expect. For example, there are four levels of service that are provided to the public: medical first response, basic life support, limited advanced life support, and advanced life support. Each increased level has the ability to provide more advanced care to patients.

Impact on Other State or Local Governmental Units

13. Estimate any increase or decrease in revenues to other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Estimate the cost increases or reductions for other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Include the cost of equipment, supplies, labor, and increased administrative costs in both the initial imposition of the rule and any ongoing monitoring.

There will be a cost associated with a municipality's failure to properly letter its EMS vehicle. The cost associated with re-lettering will be approximately \$50 per vehicle. There do not appear to be any further increases or decrease in revenue or costs to other state or local governmental units for costs of equipment, supplies, labor, and increased administrative costs.

14. Discuss any program, service, duty, or responsibility imposed upon any city, county, town, village, or school district by the rules.

MDHHS is not aware of any program, service, duty, or responsibility imposed upon any city, county, town, village, or school district by the rules, other than the requirement that proper identification of each EMS vehicle be made.

A. Describe any actions that governmental units must take to be in compliance with the rules. This section should include items such as record keeping and reporting requirements or changing operational practices.

If an EMS agency that is also a governmental unit does not have their vehicles lettered properly, they will have to purchase either vinyl or magnetic lettering to display the appropriate level of service they provide.

15. Describe whether or not an appropriation to state or local governmental units has been made or a funding source provided for any additional expenditures associated with the proposed rules.

There are no appropriations or funding sources identified for any additional expenditures associated with the proposed rules.

Rural Impact

16. In general, what impact will the rules have on rural areas?

The rule change will not have a specific impact to rural areas. All EMS agencies are expected to follow the rules in rural and urban areas.

A. Describe the types of public or private interests in rural areas that will be affected by the rules.

It is unknown what public or private interests may be affected other than consistent procedures for life support agencies in providing medical transport and care to the state as the rules will apply to all agencies statewide.

Environmental Impact

17. Do the proposed rules have any impact on the environment? If yes, please explain.

The rules do not have an impact on the environment.

Small Business Impact Statement

18. Describe whether and how the agency considered exempting small businesses from the proposed rules.

MDHHS did not consider exempting any life support agencies from the proposed rules. The rules apply equally to all life support agencies, large or small, to provide consistent care to state of Michigan citizens.

19. If small businesses are not exempt, describe (a) the manner in which the agency reduced the economic impact of the proposed rules on small businesses, including a detailed recitation of the efforts of the agency to comply with the mandate to reduce the disproportionate impact of the rules upon small businesses as described below (in accordance with MCL 24.240(1)(a-d)), or (b) the reasons such a reduction was not lawful or feasible.

The proposed changes to the rules do not have a disproportionate economic impact on life support agencies – rural, private, or municipal.

A. Identify and estimate the number of small businesses affected by the proposed rules and the probable effect on small businesses.

There are 811 EMS agencies, 3,870 vehicles, approximately 28,000 licensed EMS personnel, and 59 medical control authorities affected by this rule promulgation. There is no anticipated impact on small businesses and the number affected by the proposed rules.

B. Describe how the agency established differing compliance or reporting requirements or timetables for small businesses under the rules after projecting the required reporting, record-keeping, and other administrative costs.

There is no differing compliance or reporting requirements.

C. Describe how the agency consolidated or simplified the compliance and reporting requirements for small businesses and identify the skills necessary to comply with the reporting requirements.

There are no differing compliance and/or reporting requirements for small businesses.

D. Describe how the agency established performance standards to replace design or operation standards required by the proposed rules.

MDHHS did not establish performance standards to replace design or operation standards required by the proposed rule.

20. Identify any disproportionate impact the proposed rules may have on small businesses because of their size or geographic location.

There is no disproportionate impact on small businesses because of their size or geographic location.

21. Identify the nature of any report and the estimated cost of its preparation by small businesses required to comply with the proposed rules.

There are no new reports for any business, small or large, imposed by these rules.

22. Analyze the costs of compliance for all small businesses affected by the proposed rules, including costs of equipment, supplies, labor, and increased administrative costs.

Aside from changing the lettering on four EMS vehicles for minimal cost, there are no proposed changes in costs or fees to small businesses anticipated.

23. Identify the nature and estimated cost of any legal, consulting, or accounting services that small businesses would incur in complying with the proposed rules.

There are no costs for legal, consulting, or accounting services that small businesses would incur.

24. Estimate the ability of small businesses to absorb the costs without suffering economic harm and without adversely affecting competition in the marketplace.

There are no costs to absorb and therefore, no economic harm to small businesses.

25. Estimate the cost, if any, to the agency of administering or enforcing a rule that exempts or sets lesser standards for compliance by small businesses.

The standards are consistent for all levels of EMS agency licensure.

26. Identify the impact on the public interest of exempting or setting lesser standards of compliance for small businesses.

The safety of Michigan citizens or visitors will be at stake if any life support agency was exempted or lesser standards were allowed.

27. Describe whether and how the agency has involved small businesses in the development of the proposed rules.

The rules were developed in coordination with all EMS stakeholders in the public, and small and large businesses, over a timeframe of 2 years before rule promulgation took place.

A. If small businesses were involved in the development of the rules, please identify the business(es).

All EMS agencies, including municipal, private, and rural agencies were involved in the development through the EMSCC, their subcommittees, and public comment of all of their constituent groups.

Cost-Benefit Analysis of Rules (independent of statutory impact)

28. Estimate the actual statewide compliance costs of the rule amendments on businesses or groups.

There are no anticipated compliance costs for the proposed rule amendments, in addition to the actual costs of the lettering (see above).

A. Identify the businesses or groups who will be directly affected by, bear the cost of, or directly benefit from the proposed rules.

All EMS agencies and staff are affected by these rules. Anyone who requires EMS services will benefit from access to a safe and high quality EMS system. The four agencies that must change their lettering will bear the cost of that activity, although minimal cost is involved.

B. What additional costs will be imposed on businesses and other groups as a result of these proposed rules (i.e. new equipment, supplies, labor, accounting, or recordkeeping)? Please identify the types and number of businesses and groups. Be sure to quantify how each entity will be affected.

Other than the lettering issue, no further additional costs are anticipated.

29. Estimate the actual statewide compliance costs of the proposed rules on individuals (regulated individuals or the public). Include the costs of education, training, application fees, examination fees, license fees, new equipment, supplies, labor, accounting, or recordkeeping.

There may be training and education fees associated with obtaining and retention of EMS licenses. No other costs are anticipated.

A. How many and what category of individuals will be affected by the rules?

811 EMS agencies, 3,870 vehicles, approximately 28,000 licensed EMS personnel, and 59 medical control authorities are affected by these rules.

B. What qualitative and quantitative impact do the proposed changes in rules have on these individuals?

The impact is clearer definition of requirements, better safety standards, and higher quality patient care. There do not appear to be any quantitative impact on these individuals at this time.

30. Quantify any cost reductions to businesses, individuals, groups of individuals, or governmental units as a result of the proposed rules.

There are no anticipated cost reductions to businesses, individuals, groups of individuals, or governmental units as a result of the proposed rules.

31. Estimate the primary and direct benefits and any secondary or indirect benefits of the proposed rules. Please provide both quantitative and qualitative information, as well as your assumptions.

The benefits are improved patient outcomes and safety, transparency to patients, less confusion over rule interpretation, improved vehicle safety, quantitative benchmarks to assess the entire EMS and Trauma System through data collection and analysis, and alignment with national EMS standards.

32. Explain how the proposed rules will impact business growth and job creation (or elimination) in Michigan.

It is not anticipated that any impact on business growth and job creation or elimination will occur.

33. Identify any individuals or businesses who will be disproportionately affected by the rules as a result of their industrial sector, segment of the public, business size, or geographic location.

No individuals or businesses who will be disproportionately affected by the rules as a result of their industrial sector, segment of the public, business size, or geographic location.

34. Identify the sources the agency relied upon in compiling the regulatory impact statement, including the methodology utilized in determining the existence and extent of the impact of the proposed rules and a cost-benefit analysis of the proposed rules.

Comparisons were made with standards from CAMTS, CAAS, NAAMTA, Guidelines for the Use and Availability of Helicopter Emergency Medical Transport by the U.S. Department of Transportation, NHTSA, for consistency in standards for EMS agencies and vehicles.

A. How were estimates made, and what were your assumptions? Include internal and external sources, published reports, information provided by associations or organizations, etc., that demonstrate a need for the proposed rules.

Assumptions: the EMS system will not tolerate fee increases; citizens and visitors to rural areas expect and deserve to have the same level of care as more urban and suburban areas of the State; safety should be considered first for all EMS agencies, EMS personnel, and the public; Michigan has a unique EMS system structure, in that we utilize medical control authorities (MCAs) rather than a medical director for each EMS agency; EMS must be prepared to utilize current technologies to implement statutory requirements for regulatory activities and to provide efficient patient care; and the EMS protocols must be data driven and evidenced based. Reports: National Scope of Practice for EMS personnel from the Commission on the Accreditation of Allied Health Programs (CAAHEP), Committee on Accreditation of EMS Education Programs (CAEMSEP), and National Registry of EMTs (NREMT), National Association of EMTs (NAEMT), National Association of EMS Physicians (NAEMSP), National Organization of State Offices of Rural Health (NOSORH), Michigan Center for Rural Health (MCRH), and the National Association of State EMS Officials (NASEMSO), vehicle safety standards from NHTSA, NFPA, and CAAS-GVS, standards for helicopters and aircraft from CAMTS and NAAMTA, and ambulance agency certification standards from CAAS.

Alternative to Regulation

35. Identify any reasonable alternatives to the proposed rules that would achieve the same or similar goals.

An alternative to the rules would only be amendment of the statute.

A. Please include any statutory amendments that may be necessary to achieve such alternatives.

No statutory amendments are necessary at this time.

36. Discuss the feasibility of establishing a regulatory program similar to that proposed in the rules that would operate through private market-based mechanisms. Please include a discussion of private market-based systems utilized by other states.

There are accrediting national bodies that charge exorbitant fees for certifications. These accrediting agencies are very narrowly focused and would require an EMS agency to obtain multiple accreditations. To our knowledge, EMS agencies are regulated by every U.S. State in some capacity.

37. Discuss all significant alternatives the agency considered during rule development and why they were not incorporated into the rules. This section should include ideas considered both during internal discussions and discussions with stakeholders, affected parties, or advisory groups.

No alternatives were considered during the rule development. The proposed rules are consistent, fiscally responsible, and promote the safety and welfare of Michigan citizens.

Additional Information

38. As required by MCL 24.245b(1)(c), please describe any instructions regarding the method of complying with the rules, if applicable.

If the rule changes are approved, the MDHHS will communicate the changes to all EMS stakeholders, including: Michigan EMS agencies, Medical Control Authorities, and EMS personnel. Forms and guides will also be updated to reflect the changes and will be communicated as well.