

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:

Policy and Legislative

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Rule Set Information:

ARD assigned rule set number:

2021-31 HS

Title of proposed rule set:

Michigan Physician Orders for Scope of Treatment

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.

There are no federal rules or standards regarding the creation of the POST form. POST is a part of the National Physician Orders for Life Sustaining Treatment (POLST) Paradigm. Nationally, POLST is a movement to allow Americans better tools in communicating their healthcare wishes. POLST is a portable medical order set used in many states to allow individuals with serious, life-limiting conditions to communicate preferences on resuscitation, intubation, and artificially administered nutrition and hydration. Michigan has chosen to adopt national standards for the creation and utilization of this form. POLST has different names in different states. In Michigan, we call it Michigan Physician Orders for Scope of Treatment, or MI-POST.

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

These rules are required by state law pursuant to MCL 333.20919, 333.20192a.

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.

There is no federal standard for these rules.

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

Indiana instituted a similar POST program. Comparing Michigan's proposed rules with Indiana, they do appear to be very similar and accomplish similar requirements to legally complete these medical orders in coordination with the patient. The Indiana POST Program is an advance care planning tool that helps ensure treatment preferences are honored. It is designed for patients with advanced chronic or terminal illness or frailties. Preferences for life sustaining treatments including resuscitation, medical interventions (e.g., comfort care, hospitalization, intubation, mechanical ventilation), antibiotics, and artificial nutrition are documented as medical orders on the POST form. It must be reviewed and signed by a physician, advance practice nurse, or physician assistant to be activated. This form transfers throughout the health care system and the orders are valid in all settings.

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

The proposed rules do not exceed standards in the other states with legislation.

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

The proposed rules do not duplicate, overlap, or conflict with laws, rules, or other legal requirements.

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.

The POST form contains a medical order regarding the initiation of resuscitation if the patient suffers cessation of both spontaneous respiration and circulation, and the emergency medical services personnel has actual notice of a do-not-resuscitate order that was executed under the Michigan do-not-resuscitate procedure act, 1996 PA 193, MCL 333.1051 to 333.1067, after the POST form was validly executed. As used in this subdivision, "actual notice" means that term as defined in section 2 of the Michigan do-not-resuscitate procedure act, 1996 PA 193, MCL 333.1052. If a POST form is validly executed after a do-not-resuscitate order is executed under the Michigan do-not-resuscitate procedure act, 1996 PA 193, MCL 333.1051 to 333.1067, the medical orders indicated on the POST form are presumed to express the patient's current wishes.

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.

MCL24.232(8) does not apply to these 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.

MCL24.232(9) does not apply to these 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.

MI-POST is intended for use by an attending health professional and only for those elderly patients with advanced illness for whom, based on his or her current medical condition, death would occur within one year.

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

MI-POST is an optional form for people with serious advanced illness or frailty. It is part of an advance care planning process. It is intended to guide care only if the person cannot tell others what to do at that time.

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

The form is not currently available and the rules provide the authority for the creation and utilization of the MI-POST form.

With the creation of the MI-Post form, a physician's creates an active order set for the patient's current medical condition, which also include resuscitation and treatment decisions. They help ensure that the decisions of a patient are followed, even if the patient later lacks capacity to make decisions. Seriously ill or frail patients, especially those whose attending health professionals would not be surprised if they were to die within a year, are encouraged to complete a MI-POST form. The form takes the patient's decisions and puts them into a physician's order set that can be followed at any Michigan health care facility, as well as by first responders.

C. What is the desired outcome?

The desired outcome is to help health care professionals honor the treatment decisions of their patients through the creation of portable medical orders. Improve the quality of care through the reduction of medical errors through informed consent and allowing decisions to be made in advance.

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.

MI-POST fills a gap that cannot be met by an advance directive, or an out-of-hospital Do-Not-Resuscitate (DNR) form. Emergency Medical Services are required by law to provide aggressive treatment unless otherwise directed by a medical order. In the absence of a POST form patients will receive advanced cardiac life support, including cardiopulmonary resuscitation, endotracheal intubation, and defibrillation by emergency medical personnel based on standard protocols. In addition, DNR forms specifically address cardiac life support and are only applicable when a person is not breathing and has no pulse. The MI-POST form is more specific and addresses additional medical interventions such as intubation, transport, antibiotics, cardioversion, tube feeding and hospitalization.

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

These are new rules in compliance with MCL 333.5676.

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.

Michigan's Physician Orders for Scope of Treatment (MI-POST) form is an advance care planning tool that would include a patient's medical condition, the signatures of the patient or patient representative and attending health professional, and a list of the treatments that may be administered outside of a hospital. The form ensures patients with an advance illness have their resuscitation and treatment decisions documented. Advanced illness means a medical or surgical condition with significant functional impairment that is not reversible by curative therapies and that is anticipated to progress toward death despite attempts at curative therapies or modulation.

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

There are no rules in the affected rule that are obsolete or unnecessary that can be rescinded. This is a new rule set.

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).

Analysis of the bills determined a modest one-time fiscal implication for the Michigan Department of Health and Human Services (MDHHS) to establish an initial ad hoc advisory committee, develop a standardized POST form, promulgate rules for the use of a POST form and circumstances under which a POST form is considered valid, and establish a follow-up ad hoc advisory committee in 3 years. Regional medical control authorities must establish protocols for complying with the new Part 56B for local emergency medical services, in coordination with MDHHS, which may have one-time modest cost implications for those entities. Any of these fiscal impacts have already been realized and we would expect no significant fiscal impact on MDHHS or healthcare professionals.

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

There will be minimal fiscal impact. MDHHS will develop administrative rules and will need to maintain information on our website. This information will need be updated periodically. This will require a small portion of employees' time to maintain. An appropriation or funding source is not necessary due to the minimal fiscal impact provided by 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.

The proposed rules are being created due to legislative mandate under MCL 333.20919. There is no anticipated burden on the agency or an individual(s) in completing the form and having health facilities and professionals document the advanced care planning tool in an individual's history; whether electronic or paper file.

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

Any burdens are speculative and appear to be minimal.

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 is no anticipated increase or decrease in revenues for other state or local government units.

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

There is no impact of any program, service, duty, or responsibility imposed on any city, county, town, village, or school district by the rules.

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.

No changes are needed for governmental units to be in compliance with these rules.

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 additional expenditures for state or local government units required, therefore, no appropriation was provided.

Rural Impact

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

The rules will not have any significant impact on rural areas. MI-POST is designed to ensure that seriously ill patients can choose the treatments they want and that their wishes are honored by medical providers. A key component of the system is thoughtful, facilitated advance care planning conversations between health care professionals and patients and those close to them. Completion of a MI-POST form requires shared decision making between the health care professional signing the form and the patient, or his/her legally authorized health care representative.

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

Rural medical practices will have to enter the form into a patient's medical records.

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.

No exemptions were considered as it would discriminate against certain populations that, if not for the size of a business in their area, would not be able to request these medical orders to be documented.

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 requirement to comply with these rules is the minimum required by statute for all businesses. The impact is anticipated to be minimal given the statute's parameters.

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

This will impact all small medical practices statewide. Number is unknown, but fiscal impact is minimal.

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.

The only administrative action is placing the form in a patient's records. All providers regardless of size do this for other patient information. Costs are typically accounted for within standard medical code billing to insurance.

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.

The requirement is the minimum required by statute for all medical practices.

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

Health facilities and health providers will use the MI-POST form created by the department documenting a patients' treatment decisions and the performance standard for the business is to document that decision in a patient's medical record.

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

There is no known disproportionate impact on small institutions 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 is no known disproportionate impact on small institutions due to these proposed 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.

There do not appear to be any additional costs for small institutions to comply with these proposed rules.

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.

The agency does not anticipate any additional legal, consulting, or accounting service costs with these proposed rules.

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

The agency does not anticipate any economic harm and adverse effects to competition in complying with these proposed rules.

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 proposed rules do not exempt nor set lesser standards for compliance by small businesses.

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

The impact on the public interest by exempting or setting lesser standards for small businesses would create an inconsistent availability for patients in small health business settings to utilize the form and be able to make medical decisions on their own regarding DNR and other life-saving procedures. The use of the MI-POST form is intended to be universally available to all businesses, small or large.

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

MDHHS is required by statute under MCL 333.5675 to establish an ad-hoc rules committee with representatives of organizations to be on this committee. MDHHS' MI POST committee was comprised of 11 members, including multiple representatives from medical provider stakeholder groups.

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

Honoring Healthcare Choices; Burcham Hills; IHA Palliative Care; Gogebic Medical Center.

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

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

Statewide compliance costs are expected to be minimal. The time of a medical professional to complete the form should be able to be included within a medical procedure billing code.

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

Healthcare Association of Michigan, Michigan Health and Hospital Association, Michigan Home Care and Hospice Association, MI Assoc. of Family Physicians, Emergency Medical Personnel, Palliative Care Providers, Long term care providers, and health care professionals.

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.

No 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 is the potential for minimal labor costs associated with compiling the form and documented it within a patient's health record.

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

All medical and EMS providers will be affected by the rules.

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

The addition of this form should be welcomed by these individuals. The original form in its most current version should remain the property of the individual patient. The health care facility initiating the transfer must provide ambulance services and the receiving facility with the MI-POST form. Paper copies are permissible and valid and should be made on pink paper. Facilities may retain copies of the patient's MI-POST form. The ambulance service and receiving facility should honor the MI-POST if an emergency arises. The form is intended to respect the wishes of the patient with an advanced illness while subsequently reducing the potential for medical errors which in turn should lead to improving quality of care.

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

The form and the associated rules are not intended to produce any quantifiable cost reductions. In the absence of a POST form patients will receive advanced cardiac life support, including cardiopulmonary resuscitation (CPR), endotracheal intubation, and defibrillation by emergency medical personnel based on standard protocols.

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.

MI-POST is intended to improve the quality of patient care and reduce medical errors by creating a system that identifies patients' wishes regarding medical treatment and communicates and respects them by creating portable medical orders. It is based on the principles of informed consent and allows decision to be made ahead of a crisis.

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

These rules will have little to no impact on business growth or job creation.

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.

The health care field will have some impact by the proposed regulation. However, the impact will be minimal.

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.

House and Senate fiscal analysis; PA 157 of 2017.

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.

House and Senate fiscal analysis documentation.

Alternative to Regulation

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

There are no reasonable alternatives to the proposed rules. The requirements are required by statute.

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

There are no statutory amendments that would achieve the necessary outcomes for patients.

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.

Healthcare institutions, EMS, and other licensed health professions nationwide are regulated by state entities. It is not feasible to regulate these groups through private market-based mechanisms.

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.

There were no alternatives other than these rules because that is what was required by the MI-POST statute.

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.

MDHHS will provide the form on our website with instructions for the health facilities and staff to provide to their patients. The original form in its most current version should remain the property of the individual patient. The health care facility initiating the transfer must provide ambulance services and the receiving facility with the MI-POST form. Paper copies are permissible and valid and should be made on pink paper. Facilities may retain copies of the patient's MI-POST form. The ambulance service and receiving facility should honor the MI-POST if an emergency arises.