

**Michigan Office of Administrative Hearings and Rules**

**Administrative Rules Division (ARD)**

611 W. Ottawa Street

Lansing, MI 48909

Phone: 517-335-8658 Fax: 517-335-9512

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

**Agency Information:**

**Department name:**

Health and Human Services

**Bureau name:**

Population Health and Community Services

**Name of person filling out RIS:**

Mary Brennan

**Phone number of person filling out RIS:**

517-284-4850

**E-mail of person filling out RIS:**

BrennanM@michigan.gov

**Rule Set Information:**

**ARD assigned rule set number:**

2020-41 HS

**Title of proposed rule set:**

Definition of Infectious Agents

**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.**

No parallel federal, state, or accreditation rules or standards exist.

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

Yes – MCL 333.2843b(3) requires that MDHHS promulgate rules to define the term “infectious agent.” MCL 333.2843(4) authorizes MDHHS to promulgate rules to administer MCL 333.2843b.

**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.**

No parallel federal standards or citation exists.

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

Indiana law, IC 16-41-13, requires that the attending physician or health care provider must attach a notice to the body of a deceased individual warning if the body is infected with various communicable diseases. The statute lists numerous specific diseases, and permits inclusion of further diseases by way of rulemaking.

Illinois law, 77-1-e-500.50f requires that the body of a person who had or was suspected to have a disease that could be transmitted through contact with the body or bodily fluids be labeled with the tab “Infectious Hazard.”

Kentucky Revised Statutes Title XVIII. Public Health § 213.076(8) requires that bodies of persons who died from certain communicable diseases may be removed only under conditions prescribed by the Cabinet for Health and Family Services. It further provides that, where persons die of certain communicable diseases in a health facility, the facility must notify funeral directors of that fact.

**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 the standards in the states referred to above.

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

No laws, rules, or other legal requirements duplicate, overlap, or conflict with the proposed 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.**

No other federal, state, or local law applies to this proposed rule. The proposed rule will reduce the need to make further rule amendments going forward, facilitating more nimble changes to the list of diseases during future health crises.

**4. If MCL 24.232(8) applies and the proposed rules are more stringent than the applicable federally mandated standard, a statement of specific facts that establish the clear and convincing need to adopt the more stringent rules and an explanation of the exceptional circumstances that necessitate the more stringent standards is required.**

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, either the 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 and an explanation of the exceptional circumstances that necessitate the more stringent standards is required.**

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

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

The proposed rules are designed to ensure that funeral directors have the information necessary to take adequate precautions when handling bodies with infectious agents. Further, the rule requires MDHHS to ensure that any new communicable diseases will be added promptly on MDHHS' website for notification to physicians, other health care professionals and facilities for their safety and for the public health.

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

The proposed rule will not increase the frequency of physician reports mandated by MCL 333.2843b. New infectious agents will be added to the definition of "infectious agent" by the Registrar as necessary.

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

The proposed rule will permit the Registrar to revise the definition of "infectious agent" with greater agility, thereby better protecting funeral directors and medical examiners from novel pathogens.

**C. What is the desired outcome?**

Better protection to include funeral directors and medical examiners from novel pathogens.

**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.**

If the definition of infectious agent is not revised in a timely manner, physicians may fail to inform funeral directors and medical examiners of infectious agents present in the bodies in their possession. Lacking this important information, the funeral directors or medical examiners may not take appropriate precautions to limit the spread of infection, thereby exposing themselves or others to pathogens.

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

At present, revisions of the definition of "infectious agent" must be occurred by amendment to rule. This unnecessarily delays revisions to the definition. This issue was highlighted by the COVID-19 pandemic. Relatedly, administrative rule R. 325.173 currently permits the Michigan Department of Health and Human Services to define by policy the set of pathogens that trigger mandatory reports of infectious diseases in living persons. This longstanding practice has proven highly successful, keeping Michigan's reporting requirements nimble and up to date.

**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.**

The rule places a requirement on physicians to convey the minimum necessary information to permit funeral directors and medical examiners to protect themselves from disease.

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

There is one rule and this rule is being amended only.

**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).**

The proposed rule will eliminate the need to re-amend the rule each time a new disease needs to be added to the list of infectious agents, thereby saving the state funding and time that would otherwise be expended on rulemaking.

**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 appropriation has been made and no funding source is provided.

**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 rule places a requirement on physicians to convey the minimum necessary information to permit funeral directors and medical examiners to protect themselves from disease.

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

The rule places a requirement on physicians to convey the minimum necessary information to permit funeral directors and medical examiners to protect themselves from disease. The burden cannot be reduced while maintaining the benefit to funeral directors and medical examiners.

**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.**

MDHHS will be spared the cost of funds that would otherwise be expended on amending the rule to incorporate novel infectious agents. No other fiscal increases or decreases are expected.

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

No impact is expected in any city, town, village, or school district by promulgation of the rule.

**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.**

Physicians employed by units of government may be required to abide by the requirements of MCL 333.2843b. This amended rule would grant greater discretion to MDHHS to determine the list of "infectious agents," thereby slightly increasing the number of pathogens for which governmental physicians must make reports.

**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.**

No appropriation has been made nor any funding source provided for any expenditures associated with this proposed rule.

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

The proposed rule does not distinguish regarding the requirement of reporting to funeral directors and other medical personnel the notifications of infectious diseases, whether rural or urban.

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

Physicians in rural areas, like those in other areas, will continue to be required to make a report where infectious agents are present, consistent with MCL 333.2843b.

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

There is no anticipated impact on the environment as a result of these proposed rules.

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

All physicians, regardless of the size of their business or employer, must comply with MCL 333.2843b to adequately protect funeral directors and medical examiners.

**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.**

This rule applies equally to all physicians of all sorts, regardless of the size of their business or employer, who must comply with MCL 333.2843b to adequately protect funeral directors and medical examiners. There is no anticipated costs that are disproportionate to small businesses in this proposed rule.

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

Physicians employed by small businesses will be required to comply with MCL 333.2843b by reporting infectious agents consistent with the proposed rule. As of 2008, approximately 42,000 physicians practiced in Michigan (link: [https://www.michigan.gov/documents/healthcareworkforcecenter/Physician\\_Profile\\_MHC\\_FINAL\\_FEB09\\_267821\\_7.pdf](https://www.michigan.gov/documents/healthcareworkforcecenter/Physician_Profile_MHC_FINAL_FEB09_267821_7.pdf)). As of 2018, approximately 30 percent of Michigan physicians were in private practice (link: <https://www.mha.org/Newsroom/ID/1620/National-Survey-Provides-State-of-the-Union-of-the-Medical-Profession>). Therefore, approximately 12,600 physicians working in small businesses will continue to have infectious agent reporting obligations under this amended rule.

**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.**

Physicians of all sorts, regardless of the size of their business or employer, must equally comply with MCL 333.2843b to adequately protect funeral directors and medical examiners. This includes the required reporting and record-keeping.

**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 agency has attempted to consolidate and simplify the compliance and reporting requirement in a centralized location that allows it to update the listing of those communicable diseases promptly for all businesses and physicians of all sorts, regardless of the size of their business or employer, in order to comply with MCL 333.2843b to adequately protect funeral directors and medical examiners.

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

Compliance with the reporting obligation is the same marker of performance.

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

As the reporting requirement applies to all physicians, the impact applies equally to physicians regardless of their practice.

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

The statute and rule hold all physicians in the state accountable for reporting requirements. There are no known additional expenses anticipated by this rule.

**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.**

The proposed rule does not significantly expand the reporting requirements beyond those already in existence, and thus do not entail calculable additional expenses.

**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 known costs of any legal, consulting, or accounting services that small businesses would incur in complying with the 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.**

As above, costs of this proposed rule do not measurably exceed the costs already incurred under the scheme set forth by MCL 333.2843b.

**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 rule does not exempt or sets lesser standards for small businesses. The expectations of reporting in compliance with the statute is the same throughout the state for all businesses.

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

Physicians of all sorts, regardless of the size of their business or employer, must comply with MCL 333.2843b to adequately protect funeral directors and medical examiners. It is in the public's best interests to require all businesses to report to protect those who come into contact with the deceased for their own protection statewide.

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

Small businesses were not involved in the development of the proposed rules.

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

Small businesses were not involved in the development of the proposed rules.

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

Costs of this proposed rule do not measurably exceed the costs already incurred under the scheme set forth by MCL 333.2843b.

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

Physicians will continue to bear the burden of reporting under the proposed rule. Funeral directors and medical examiners will benefit from the reporting requirements to protect themselves and those they come in contact with in the event they are subjected to communicable disease from the deceased.

**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.**

Costs of this proposed rule do not measurably exceed the costs already incurred under the scheme set forth by MCL 333.2843b.

**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 are no anticipated statewide compliance costs that otherwise exist under the reporting requirements by statute.

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

All physicians statewide, all funeral directors, all medical examiners, and ultimately, the safety of the public as a result of the notifications from physicians to the funeral directors and medical examiners to ensure their safety and that of their families when dealing with the deceased.

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

The rules ensure notification to all funeral directors and medical examiners statewide to protect themselves and their families from being subjected to and possibly spreading a communicable disease.

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

Providing information to funeral directors and medical examiners regarding the presence of infectious agents in a body in their possession enables them to avoid becoming infected with that agent, thereby eliminating unnecessary medical treatment and reducing the rate of injury or death amongst funeral directors and medical examiners.

**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.**

All physicians must report so all funeral directors and medical examiners have the same protections statewide. Providing information to funeral directors and medical examiners regarding the presence of infectious agents in a body in their possession enables them to avoid becoming infected with that agent, thereby eliminating unnecessary medical treatment and reducing the rate of injury or death amongst funeral directors and medical examiners.

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

There is no known impact on business growth and job creation from these rules in Michigan.

**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 statute already requires reporting by all physicians statewide. The propose rule does not disproportionately affect the 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.**

Examination of MCL 333.2843b and the existing rule; discussions with the Vital Statistics section of MDHHS, discussions with stakeholders involved in the minimization of infection caused by the current pandemic, COVID-19, including MDHHS staff involved with the population and health section, and research via the internet.

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

There were no estimates made. The reporting requirement remains and ensuring timely updates to any and all communicable diseases and the prevention of spreading to funeral directors and medical examiners based on the current spread of COVID-19 was the catalyst in the change of the rules to quickly disseminate information to those who require the information for their safety and the safety of others.

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

There are no other reasonable alternatives to the proposed rule that would achieve the same or similar goals.

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

There are no alternatives to the proposed rules.

**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.**

No private market-based system could compel the provision of infectious agent information from physicians to funeral directors and medical examiners.

**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.**

The rule could be amended to permanently include COVID-19, but to leave in place the regime of defining infectious agents in the rule itself, as opposed to in a list referred to by rule. This possibility was rejected, as the current regime impedes agile inclusion of novel infectious agents on the list, and necessitates expensive and time consuming rule amendments each time a new infectious agent is added.

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

DHHS will develop a new website location for the current and future listing of any and all infectious agents and the medical industry, funeral director industry and medical examiners will be made aware of the changes once the rule is permanently promulgated.