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:

Labor and Economic Opportunity

Bureau name:

MIOSHA

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Rule Set Information:

ARD assigned rule set number:

2023-8 LE

Title of proposed rule set:

Ionizing Radiation Rules Governing the Use of Radiation Machines

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.

Prior to the proposed rules, MIOSHA did not require specific training for non-exempted medical x-radiation technologists. The proposed rules would be parallel to the American Registry of Radiologic Technologists (ARRT) medical x-radiation technology training requirements.

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

The proposed rules are not required by state law or federal mandate.

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.

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

Ohio – Ohio requires licensing (more stringent).

Wisconsin – Requires ARRT certification or limited scope examination, state issues the license or permit.

Indiana – Requires a license; Indiana issues the license after an approved examination. The ARRT examination is one of the approved examinations.

Illinois – issues accreditation, must pass an approved test. The ARRT limited examination is required for limited scope accreditation.

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 similarly situated states listed above.

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 any laws, rules, and/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.

MIOSHA coordinated with ARRT to draft proposed rules to require and regulate formal documented x-radiation technology training.

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 because there is no federally mandated standard.

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 because there is no federally mandated standard.

Purpose and Objectives of the Rule(s)

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

The behavior and frequency of behavior that the proposed rules are designed to alter is to ensure adequate training for non-exempt medical x - radiation technologists. Currently, many non-exempt x-radiation technologists may not have documented formal training. These proposed rules would formalize the content and recordkeeping of the training. The frequency of the behavior is when medical x-radiation technologists perform radiologic procedures.

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

There is no estimated change in the frequency of the targeted behavior expected from the proposed rules.

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

Currently, there are no specific training requirements for non-exempt medical x-radiation technologists. The desired behavior/practice for all non-exempt medical x-radiation technologists is to provide formal documented training.

C. What is the desired outcome?

The desired outcome for all non-exempt medical x-radiation technologists is to receive formal documented training to improve the quality of images and hazards to patients and personnel.

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 medical x-radiation technologists are not properly trained, there is an increased chance that the improper performance of medical x-radiation results in unnecessary radiation exposure and poor examinations, which can lead to potential hazards to employees and severe medical consequences to the patient.

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

Currently, there are no specific rules. The proposed rules are a new ruleset.

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 proposed rules protect the health, safety, and welfare of Michigan citizens by preventing unnecessary exposure to radiation. The proposed rules do allow medical providers to provide their own training.

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

There are no current rules.

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).

The fiscal impact on the agency will result in additional time spent reviewing employee training credentials. There is no feasible way to determine actual additional time required to perform the reviews.

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

The agency has not made any requests for an increased appropriation associated with the proposed 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 necessary and suitable to ensure proper training of non-exempt medical x-radiation technologists. The potential increased medical repercussions far outweigh the potential increased costs of properly training the medical x-radiation technologists.

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

The proposed rules are necessary and suitable to ensure proper training of non-exempt medical x-radiation technologists. The potential increased medical repercussions far outweigh the potential increased costs of properly training the medical x-radiation technologists.

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.

Our research indicated there were approximately 20 government facilities that operate medical x-radiation equipment. Depending on the use of these machines in these facilities, there could be an increase in administrative costs due to additional training of staff.

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

The proposed rules would require any governmental program that has operators performing medical x-radiation technology to ensure adequate training for those operators.

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.

The proposed rules would require any governmental unit that has operators performing medical x-radiation technology to ensure adequate training for those operators.

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 requests for state or local governmental units have been made for any additional expenditures associated with the proposed rules.

Rural Impact

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

The proposed rules may have an impact on facilities with operators performing medical x-radiation technology. The impact may include additional training requirements/costs.

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

The proposed rules may affect both the public and private interests of non-healthcare system-affiliated chiropractors, podiatrists, and independent healthcare clinics.

Environmental Impact

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

The proposed rules will not have any impact on the environment.

Small Business Impact Statement

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

The proposed rules did not consider exempting small businesses.

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 rules protect the health, safety, and welfare of Michigan citizens by preventing unnecessary exposure to radiation. The proposed rules do allow medical providers to provide their own training.

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

The estimated number of small businesses affected by the proposed rules includes 315 podiatrists, 968 chiropractors, 1,045 healthcare clinics, and 25 radiology labs for a total of approximately 2,300 healthcare providers.

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.

MIOSHA did not establish differing compliance or reporting requirements or timetables for small businesses.

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.

MIOSHA did not consolidate or simplify the compliance and reporting requirements for small businesses. The skills necessary to operate a healthcare facility should be sufficient to comply with the reporting requirements.

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

No performance standards were established in the proposed rules.

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

The proposed rules protect the health, safety, and welfare of Michigan citizens by preventing unnecessary exposure to radiation. The proposed rules do allow medical providers to provide their own training.

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 proposed rules do not require small businesses to prepare a report.

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 is no practical way to determine the expected costs due to the various types of facilities and their current level of training.

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.

No additional legal, consulting, or accounting services will be required as a result of the proposed rule changes.

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

There is no practical way to determine the expected costs due to the various types of facilities and their current level of training.

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.

There would be no additional costs to the agency.

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

Allowing exemptions or allowing lesser standards of compliance for small businesses could potentially injure the general public and the employees employed by small businesses.

- **27.** Describe whether and how the agency has involved small businesses in the development of the proposed rules. MIOSHA did not involve small businesses 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.

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 is no practical way to determine the expected costs due to the various types of facilities and their current level of training.

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

Any facility that utilizes medical x-radiation technology as defined in the proposed rules.

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.

Larger facilities (i.e., hospitals and affiliated clinics) will not be affected by additional costs because they already exceed the proposed rules. Independent facility's additional costs include recordkeeping, training, and labor burdens. There is no practical way to determine the expected costs due to the various types of facilities and their current level of training.

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 no practical way to determine the expected costs due to the various types of facilities and their current level of training.

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

There is no practical way to determine how many and what category of individuals will be affected due to the various types of facilities and their current level of training.

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

The qualitative impact would be that image quality would be improved, and this would reduce unnecessary operator exposure to radiation. There is no feasible way to measure these reductions in exposure to individuals.

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

There should not be any cost reductions and it would be difficult to quantify any 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 primary and direct benefits and any secondary or indirect benefits of the proposed rules would be to reduce unnecessary exposure to radiation and reduces the number of re-takes and improves image quality.

- 32. Explain how the proposed rules will impact business growth and job creation (or elimination) in Michigan.
 - The proposed rules should not have a significant impact on business growth and job creation (or elimination) 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 proposed rules will impact medical x-radiation operators and businesses that employ medical x-radiation operators in facilities all across the state of Michigan, independent of 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.

The MIOSHA agency relied on the suggested state regulations from The Conference of Radiation Control Program Directors (CRCPD). MIOSHA reviewed the requirements from ARRT. In addition, MIOSHA analyzed adjacent states and their medical x-radiation operator requirements.

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.

MIOSHA agency relied on the suggested state regulations from CRCPD. The ARRT demonstrated a need for the proposed rules. In addition, MIOSHA analyzed adjacent states and their medical x-radiation operator requirements.

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 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 statutory amendments that may be necessary to achieve such alternatives for 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.

There is no feasibility of establishing a regulatory program similar to that proposed in the rules that would operate through private market-based mechanisms. MIOSHA analyzed the surrounding states (i.e., Ohio, Wisconsin, Illinois, Indiana, and Minnesota). The states listed above have established an internal regulatory program.

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.

MIOSHA considered the ARRT limited scope testing but chose not to use that method due to the increased costs and responsibilities required under ARRT requirements for non-exempt medical x-radiation technologists.

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.

No applicable instructions.