

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:

Licensing and Regulatory Affairs

Bureau name:

Bureau of Professional Licensing

Name of person filling out RIS:

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Rule Set Information:

ARD assigned rule set number:

2023-36 LR

Title of proposed rule set:

Osteopathic Medicine and Surgery – General Rules

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 parallel federal rules or standards set by a state or national licensing agency or accreditation association.

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

Under MCL 333.16287, the department, in consultation with the board, shall promulgate rules to implement MCL 333.16284 and MCL 333.16285.

Under MCL 333.17531, an applicant, in addition to completing the requirements for the degree in osteopathic medicine and surgery, shall complete a period of postgraduate education to attain proficiency in the practice of the profession as prescribed by the board in rules as a condition for more than limited licensure.

Under MCL 333.17533, the board shall promulgate rules requiring each applicant for license renewal to complete as part of the continuing education requirement of subsection (1) an appropriate number of hours or courses in pain and symptom management.

No federal mandate demands the rules.

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.

The rules do not exceed a federal standard or law.

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

Licensure of osteopathic medical doctors is necessary in Michigan under MCL 333.17511. The rules specify the conditions and requirements for licensure, relicensure, renewal, and continuing education.

All seven of the other Great Lakes states have rules regulating the licensing of osteopathic medical doctors, as listed below:

Illinois: Applicants for licensure must have good moral character, graduate from an osteopathic medical education program, complete postgraduate clinical training, and successfully pass Steps 1, 2, and 3 of the United States Medical Licensing Examination (USMLE) prior to obtaining full licensure.

Indiana: Applicants for licensure must not have a conviction for a crime that has a direct bearing on the applicant's ability to practice competently, must possess the degree of doctor of osteopathic medicine from an approved osteopathic medical school, complete postgraduate clinical training, and successfully pass Levels 1, 2, and 3 of the Comprehensive Osteopathic Medical Licensing Examination of the United States (COMLEX-USA) or Steps 1, 2, and 3 of the USMLE prior to obtaining full licensure.

Minnesota: Applicants for licensure must show good moral character, not be under license suspension or revocation by the licensing board of the jurisdiction in which the misconduct occurred, have graduated from an accredited osteopathic medical school, completed clinical medical training, and successfully pass Levels 1, 2, and 3 of the COMLEX-USA or Steps 1, 2, and 3 of the USMLE prior to obtaining full licensure.

New York: Applicants for licensure must have good moral character, graduated from an accredited osteopathic medical program, complete postgraduate clinical training, and successfully pass Levels 1, 2, and 3 of the COMLEX-USA or Steps 1, 2, and 3 of the USMLE prior to obtaining full licensure.

Ohio: Applicants for licensure must have good moral character, graduated from an accredited osteopathic medical school, complete postgraduate clinical training, and successfully pass Levels 1, 2, and 3 of the COMLEX-USA or Steps 1, 2, and 3 of the USMLE prior to obtaining full licensure.

Pennsylvania: Applicants for licensure must have good moral character, graduated from an accredited osteopathic medical college, received a passing score on the practical examination in osteopathic diagnosis and manipulative therapy developed and administered by the board or a designated professional testing organization, complete postgraduate clinical training, and successfully pass Levels 1, 2, and 3 of the COMLEX-USA prior to obtaining full licensure.

Wisconsin: Applicants for licensure must have graduated from an accredited osteopathic medical college, complete postgraduate clinical training, and successfully pass Levels 1, 2, and 3 of the COMLEX-USA or Steps 1, 2, and 3 of the USMLE prior to obtaining full licensure.

When compared to other Great Lakes states, Michigan's licensure requirements for osteopathic medical doctors are like other Great Lakes states.

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

Statute demands promulgation of rules related to licensure. The rules do not exceed the licensing requirements of other states.

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

There are no federal regulations for licensing of osteopathic medical doctors. There are no laws, rules, or other legal requirements that 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.

Review of applicable statutory law avoided unnecessary duplication in the rules. There are no other federal or local laws applicable to this activity.

Purpose and Objectives of the Rule(s)

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

The specific topics that the proposed rules address, and the purpose of the proposed rules is set forth below:

R 338.111, R 338.114, R 338.120, R 338.123, R 338.125, R 338.127, R 338.133, include revisions to follow current drafting standards and edits to supply clarification for easier reading.

R 338.119: This rule pertains to delegation of prescribing controlled substances to an advanced practice registered nurse and limitations. The rule revision removes the prohibition on delegation of a drug or device individually, in combination, or in succession, for a woman known to be pregnant with the intention of causing either a miscarriage or fetal death.

R 338.121: This rule pertains to accreditation standards for osteopathic medical schools and residency programs. It sets forth the standards for accreditation of osteopathic medical schools and postgraduate training programs. The rule revision updates accreditation standards.

R 338.129: This rule pertains to examinations and limitations. The rule revision lowers the number of allowed attempts to pass any level of the COMLEX-USA from six attempts to four attempts, to remain consistent with the National Board of Osteopathic Medical Examiners (NBOME) and ends the requirement that an applicant shall successfully pass all steps of the COMLEX-USA within seven years after the date that the applicant first passed a step of the COMLEX-USA.

R 338.141: This rule pertains to license renewals. The rule clarifies the period in which a licensee must request a waiver of continuing education.

R 338.143: This rule pertains to acceptable continuing education, requirements, and limitations. The rule clarifies that a licensee who completes implicit bias training under R 338.7004 may also use that training toward fulfillment of continuing education requirements and that non-Accreditation Council for Continuing Medical Education (ACCME) accredited providers engaging in joint providership with ACCME accredited providers also qualify as acceptable providers of continuing education.

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

Promulgation of rules related to licensure is necessary under statute. This supplies a regulatory framework for the practice of osteopathic medicine and surgery. The proposed changes supply greater clarity to licensees and aid in understanding the requirements of the rules.

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

Statute regulates the practice of osteopathic medicine and surgery. This mandates licensure for provision of those services. Adding clarifications on points that may have been ambiguous under prior rules will make compliance easier for applicants and licensees.

C. What is the desired outcome?

Regulation is necessary for individuals who wish to practice as osteopathic medical doctors. By improving and clarifying the rules, applicants and licensees should find compliance easier. This should result in fewer questions, fewer regulatory problems, and greater safety and protection of the public.

5. 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.

Outdated rules create conflict and confusion for osteopathic medical doctors. The proposed rules update previously adopted rules. Changes made specifically address the following:

R 338.119 pertains to delegation of prescribing controlled substances to an advanced practice registered nurse and limitations. The rule revision removes the burdensome prohibition on delegation of a drug or device individually, in combination, or in succession, for a woman known to be pregnant with the intention of causing either a miscarriage or fetal death.

R 338.121 pertains to accreditation standards for osteopathic medical schools and residency programs. Outdated standards supply little help or guidance about proper training of osteopathic medical doctors. The updated standards ensure future licensees are properly qualified.

R 338.129 pertains to examinations and limitations. The rule revision keeps consistency with the NBOME's allowed COMLEX-USA attempts requirement and ends the seven-year requirement to pass all steps of the COMLEX-USA, as the requirement is not necessary to show competence.

R 338.141 pertains to license renewals. The rule clarifies when the department must receive a request for a waiver of continuing education.

R 338.143 pertains to acceptable continuing education. The rule clarifies the use of implicit bias training toward continuing education requirements and clarifies the acceptability of non-ACCME providers engaged in joint providership with ACCME accredited providers supplying continuing education.

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

The proposed rule set supplies clarity to all rules on licensure.

6. 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 supply a regulatory mechanism for the practice of osteopathic medicine and surgery. To protect the health, safety, and welfare of Michigan's citizens, it is important that members of the profession adhere to educational and professional standards. The rules ensure that applicants receive proper education and training prior to licensure and that licensees are competent to practice. There is no less burdensome way to ensure that applicants and licensees satisfy minimum requirements for practice.

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

There are no rules in this rule set that are obsolete or unnecessary.

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.

8. 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 is no expected fiscal impact on the agency for promulgating the proposed rules.

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

There has been no agency appropriation for the proposed rules because there are no expected agency expenditures associated with the proposed rules.

10. 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 supply a mechanism for the licensing and regulation of individuals in this state, as mandated by statute. Applicants and licensees will continue to have a cost related burden associated with licensing, renewal, or relicensure. The cost of licensure for an Educational Limited Osteopathic Medical Doctor is \$93.60. The cost of renewal for an Educational Limited Osteopathic Medical Doctor is \$33.00. The cost of licensure for a Licensed Osteopathic Medical Doctor by examination or endorsement is \$375.00. The cost of renewal for a Licensed Osteopathic Medical Doctor is \$314.40. The cost of relicensure for an Educational Limited Osteopathic Medical Doctor is \$113.60. The cost of relicensure for a Licensed Osteopathic Medical Doctor is \$395.00.

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

The rules are necessary to supply a mechanism for licensing and regulation of the profession. The rules are not more restrictive than allowed by statute. Despite the cost related burden of licensing, the rules and regulations are necessary to supply a framework of standards for educational and licensure requirements.

Impact on Other State or Local Governmental Units

11. 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 expected increase or decrease in revenues to other state or local government units, nor are there cost increases or reductions on other state or local government units expected because of the proposed rules.

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

The proposed rules do not impose any program, service, duty, or responsibility upon any city, county, town, village, or school district.

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 action is necessary for governmental units to follow the rule(s).

13. 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.

State and local government units will incur no added expenditures because of implementing the proposed rules. Therefore, no appropriation or funding source is necessary.

Rural Impact

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

There is no expected disparate impact on rural areas because of the proposed rules.

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

There is no expected disparate impact on public or private interests in rural areas because of the proposed rules.

Environmental Impact

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

No, the proposed rules will have no impact on the environment.

Small Business Impact Statement

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

The Michigan Public Health Code authorizes the board and the department to regulate individuals with osteopathic medical doctor licenses, not small businesses. Even if a licensee's practice qualified as a small business, the department could not exempt the licensee's small business because it would create disparity in the regulation of the profession.

17. 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.

There is no expected economic impact on small businesses because of the proposed rules. The proposed rules affect individual licensees rather than small businesses.

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

The department does not collect or have access to information that would allow it to find and estimate the potentially affected number of small businesses. It is impossible to estimate the number of small businesses affected by the proposed rules. The only small businesses affected by these rules are health practitioners practicing in small business settings. The department does not track or have access to this type of information since it is not a data repository.

The rules do not affect the operation of the small business. The probable impact on small business is small.

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.

Because the proposed rules pertain to individuals and not small businesses, they do not have differing compliance or reporting requirements or timetables for small businesses. They are unnecessary for the proposed rules.

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 proposed rules do not impose any reporting requirements.

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

The agency did not set up performance standards to replace design or operation standards.

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

The proposed rules affect individual licensees rather than small businesses. Therefore, there is no expected disproportionate impact on small businesses based on size or geographic location because of the rules.

19. 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 need any reports. There are no reports that a small business would have to complete.

20. 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 expectation of an effect on small businesses because of the proposed rules, nor are there any added costs, because the proposed rules apply to individuals and not businesses.

21. 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 proposed rules, which apply to individuals and not businesses, should not create a need for any legal, consulting, or accounting services for small businesses to be able to follow the proposed rules.

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

Since the rules affect individual licensees rather than small businesses, there is no expected cause of economic harm or for the rules to adversely affect a small business' competition in the marketplace.

23. 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 impose requirements on individual licensees rather than small businesses. Even if a licensee's practice qualifies as a small business, the department could not exempt the licensee's small business because it would create disparity in regulation of the profession. Therefore, exempting or setting lesser standards of competence for small businesses is not in the best interest of the public.

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

The department is not able to exempt licensees that own a small business. If the department exempted small businesses, it would create disparity in the regulation of a profession and have a negative impact on public safety.

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

The department worked with the Michigan Board of Osteopathic Medicine and Surgery in the development of the proposed rules. The board is composed of professional and public members. Some members of the board may work in a small business, but the members were not involved in the development of the rules as representatives of small businesses.

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

No small businesses took part in the development of the rules.

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

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

There are no estimated compliance costs with these rule amendments on businesses or groups.

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

The proposed rules directly affect licensees. Licensees bear the cost of, and directly benefit from 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.

There will be no expected added costs imposed upon licensees because of compliance with these proposed rules.

27. 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.

Applicants and licensees will continue to have a cost related burden associated with licensing, renewal, or relicensure. The cost of licensure for an Educational Limited Osteopathic Medical Doctor is \$93.60. The cost of renewal for an Educational Limited Osteopathic Medical Doctor is \$33.00. The cost of licensure for a Licensed Osteopathic Medical Doctor by examination or endorsement is \$375.00. The cost of renewal for a Licensed Osteopathic Medical Doctor is \$314.40. The cost of relicensure for an Educational Limited Osteopathic Medical Doctor is \$113.60. The cost of relicensure for a Licensed Osteopathic Medical Doctor is \$395.00.

Currently there are approximately 9,325 licensed osteopathic medical doctors and 1,828 licensed educational limited osteopathic medical doctors. If all 9,325 licensed osteopathic medical doctors and 1,828 licensed educational limited osteopathic medical doctors continue to renew their licenses, the estimated actual statewide compliance cost would be $(9,325 \times \$314.40) + (1,828 \times \$33.00) = \$2,992,104.00$.

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

There are approximately 9,325 licensed osteopathic medical doctors and 1,828 licensed educational limited osteopathic medical doctors. The rules affect all individuals who seek licensure as osteopathic medical doctors.

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

The qualitative impact of the proposed rules on the citizens of Michigan will be that they will know a licensee who supplies services has achieved the level of education and training necessary to meet the minimum requirements for licensure. The quantitative impact of the proposed rules on the citizens of Michigan is that there may be an increase in the cost of services due to licensure, however, ensuring that the health, safety, and welfare of Michigan citizens receive proper protection outweighs those costs.

The qualitative impact on licensees and applicants by the proposed rules will be the knowledge that they and their peers have achieved the minimum requirements for licensure and can appropriately support the needs of the citizens of Michigan. The quantitative impact on licensees and applicants by the proposed rules is that they will have credentials that will meet the minimum requirements of licensure. These credentials will allow them to have access to job opportunities and compensation in line with their education and work experience.

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

There are no expected reductions in costs to businesses, individuals, groups of individuals, or governmental units because of the proposed rules.

29. 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 proposed rules use clear, concise language, and implement the statutory requirements for licensing. The clear, concise language allows the public, licensees, and schools to better understand the requirements for licensure.

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

There is no expected significant impact on business growth, job growth, or job elimination because of the rules.

31. 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 department does not expect any disproportionate effect on any individuals or businesses by their industrial sector, segment of the public, business size, or geographical location.

32. 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.

American Osteopathic Association:
<https://osteopathic.org/>

Accreditation Council for Graduate Medical Education (ACGME):
<https://www.acgme.org/>

National Board of Osteopathic Medical Examiners (NBOME):
<https://www.nbome.org/>

Coalition for Physician Enhancement (CPE):
<https://www.cpehq.org/>

Illinois:
<https://idfpr.illinois.gov/profs/physicians.html>

Indiana:
<https://www.in.gov/pla/professions/medical-physicians-and-osteopathic-physicians-home/>

Minnesota:
<https://mn.gov/boards/medical-practice/>

New York:
<https://www.op.nysed.gov/physicians>

Ohio:
<https://med.ohio.gov/>

Pennsylvania:
<https://www.dos.pa.gov/ProfessionalLicensing/BoardsCommissions/OsteopathicMedicine/Pages/default.aspx>

Wisconsin:
<https://dsps.wi.gov/pages/Professions/Physician/Default.aspx>

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.

Since statute mandates the rules, no estimates were necessary.

Alternative to Regulation

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

Since statute mandates the rules, there are no reasonable alternatives to the proposed rules.

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

Since statute mandates the rules, there are no reasonable alternatives to the proposed rules.

34. 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.

Since statute mandates the rules, private market-based systems cannot serve as an alternative. The licensing and regulation of osteopathic medical doctors are state functions, so a regulatory program independent of state intervention cannot be set up. One could consider osteopathic medical doctor professional associations as regulatory mechanisms that are independent of state intervention; however, these professional organizations would provide the public with significantly less protection because membership in these organizations is voluntary. This means an individual who meets the membership requirements, but does not join, would still be able to practice and there would be no way to ensure the individual's competency or hold the individual accountable for harm done to clients.

No other states in the Great Lakes region use a private, market-based system to regulate licensed osteopathic medical doctors.

35. 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.

Since statute mandates the rules, there are no reasonable alternatives to the proposed rules. There were no alternatives that the department considered to achieve the intended changes. They are necessary for the administration and enforcement of the licensing process.

Additional Information

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

The rules include the instructions for compliance.