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Administrative Rules Division (ARD)
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REGULATORY IMPACT STATEMENT and COST-BENEFT ANALYSIS (RIS)

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Rule Set Information:
ARD assigned rule set number:
2021-43 LR
Title of proposed rule set:
Genetic Counseling - 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.

The rules require, as a condition of licensure, evidence of certification by the American Board of Genetic Counseling, Inc., (ABGC), or the American Board of Medical Genetics and Genomics (ABMGG).

A. Are these rules required by state law or federal mandate?
Promulgation of the rules is a requirement under state law, including MCL 333.16145, 333.16148, 333.16287, 333.17091, 333.17092, and 333.17096, as well as Executive Reorganization Nos. 1991-9, 1996-2, 2003-1 and 2011-4, MCL 338.3501, 445.2001, 445.2011, and 445.2030.

No federal mandate requires 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 genetic counselors is necessary in Michigan due to PA 624 of 2018. Under MCL 333.17091, the department, in consultation with the board, shall promulgate rules that specify the minimum standards for licensure, temporary licensure, and license renewal of genetic counselors. The rules specify the conditions and requirements for licensure, relicensure, renewal, and continuing education.

Five of the 7 other Great Lakes states have rules regulating the licensing of genetic counselors, as listed below:

Illinois – Applicants for licensure must either hold a masters-level genetic counseling degree from an ABGC or an ABMGG accredited school, be a licensed physician, or have a doctoral degree from an ABMGG accredited school. Applicants must pass an examination provided by either the ABGC or the ABMGG. Applicants must hold current certification from either the ABGC or the ABMGG. Licensees must obtain 30 continuing education contact hours over the course of a 2-year license cycle to renew their license.

Indiana – Applicants for licensure must either hold a masters-level genetic counseling degree from an ABGC accredited school or have a doctoral degree from an ABMGG accredited school. Applicants must pass an examination provided by either the ABGC or the ABMGG. Licensees must obtain 50 continuing education contact hours over the course of a 2-year license cycle to renew their license.

Minnesota – Applicants for licensure must hold a masters-level genetic counseling degree from an ABGC accredited school and have a current certification from either the ABGC or the ABMGG. Licensees must obtain 50 continuing education contact hours over the course of a 2-year license cycle to renew their license.

New York – Does not regulate genetic counselors.

Ohio – Applicants for licensure must hold a masters-level genetic counseling degree from an ABGC accredited school and have a current certification from the ABGC. Licensees must obtain 30 continuing education contact hours over the course of a 2-year license cycle to renew their license.

Pennsylvania – Applicants for licensure must hold a masters-level human genetics or genetic counseling degree from either an ABGC accredited school or ABMGG accredited school. Applicants must pass an examination provided by either the ABGC or the ABMGG. Licensees must obtain 30 continuing education contact hours over the course of a 2 -year license cycle to renew their license.

Wisconsin – Does not regulate genetic counselors.

When compared to other Great Lakes states, Michigan's licensure requirements for genetic counselors 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.

MCL 333.17091 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.

Michigan regulates the practice of genetic counseling in the Public Health Code, Article 15, Part 170 of PA 368 of 1978, MCL 333.17091 to MCL 333.17097. Further, Article 15, Part 161 of the Code, MCL 333.16101 to MCL 333.16349, applies to all regulated health professions.

There are no federal regulations for genetic counselors. There are no other 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.

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.

There is no applicable federal mandate for these 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.

There is no applicable federal mandate for these rules.

Purpose and Objectives of the Rule(s)

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

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

R 338.2455, 338.2461, R 338.2471, R 338.2473 include clean-up, clarifying language, reorganization, and typographical revisions to the language in the current rules.

R 338.2457. This rule pertains to identifying human trafficking. It sets forth the requirements for training on identifying victims of human trafficking. The rule revision inserts a date of promulgation.

R 338.2462. This new rule pertains to licensure by endorsement. It sets forth the requirements for licensure by endorsement.

R 338.2463. This rule pertains to relicensure. It sets forth the qualifications for relicensure. The rule revision revises the requirements for verification of licenses held in other jurisdictions.

R 338.2465. This rule pertains to license renewal qualifications. It sets forth the qualifications for renewal of a license. The rule revision clarifies that a temporary-licensed genetic counselor may renew the temporary license 4 times.

R 338.2481. This proposed rule pertains to certification. It sets forth the requirement of holding active certification with the ABGC or the ABMGG as a condition of licensure. The rule revision includes a requirement that a licensee shall report to the department a change in active candidate status no later than 30 days after the change occurs.

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 MCL 333.17091. This supplies a regulatory framework for the practice of genetic counseling.

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

Statute regulates the practice of genetic counseling. This mandates licensure for provision of these services. The proposed revised rules supply clarifications to current rules. These additions will make compliance easier for applicants and licensees.

C. What is the desired outcome?

Licensure and regulation are necessary for individuals who wish to practice as genetic counselors. 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.

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.

Outdated rules create conflict and confusion for genetic counselors. The proposed rules include one new rule and update previously adopted rules. Changes made specifically address the following:

R 338.2457 pertains to identifying human trafficking. A rule without specific compliance dates can create confusion for applicants and licensees. Including specific dates of promulgation aids applicants and licensees in following this rule.

R 338.2462 pertains to licensure by endorsement. Minimum requirements for licensure by endorsement are necessary in the administrative rules set. The rule supplies requirements for licensure by endorsement.

R 338.2463 pertains to relicensure. The rule revision clarifies the proof of requirements an applicant licensed in another jurisdiction must satisfy for verification of a license.

R 338.2465 pertains to license renewal qualifications. The rule revision clarifies the number of times a temporary-licensed genetic counselor may renew the temporary license.

R 338.2481 pertains to certification. It sets forth the requirement of holding active certification with the ABGC or the ABMGG as a condition of licensure. The rule revision clarifies how soon a licensee must report a change in active candidate status to the department.

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

The proposed rule set updates requirements, corrects typographical errors, and supplies clarity to all rules on licensure.

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 supply a regulatory mechanism for the practice of genetic counseling. 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.

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

None of the rules in the rule set 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.

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

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

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

There has been no agency appropriation for the proposed rules because there are no expected agency expenditures 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 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 as well as costs related to ABGC or ABMGG certification. The cost of licensure for a Temporary – Licensed Genetic Counselor is $280.00. The cost of renewal for a Temporary – Licensed Genetic Counselor is $50.00. The cost of licensure for a Genetic Counselor is $392.00. The cost of renewal for a Genetic Counselor is $162.00. The cost of relicensure for Temporary – Licensed Genetic Counselor is $300.00. The cost of relicensure for a Genetic Counselor is $412.00.

ABGC: The examination fee for ABGC certification is $900 for first time applicants, $800 for repeat applicants.

ABMGG: The application fee for one (1) specialty is $680, $435 for re-examinees. An application for two (2) specialties is $735. The general exam costs $950, the specialty and subspecialty exams costs $1050.

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

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 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.

14. 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).

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.

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

16. 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 of public or private interests on rural areas because of the proposed rules.

Environmental Impact

17. 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

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

The public health code authorizes the board and the department to regulate individuals with genetic counseling 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.

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.

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 businesses. 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.

20. 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.

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 need any reports.

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 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.

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 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 comply 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.

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.

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 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 compliance for small businesses is not in the best interest of the public.

26. 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 a disparity in the regulation of a profession and have a negative impact on public safety.

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

Development of the proposed rules involved consultation with the Michigan Board of Medicine, whose members include small business employees.

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

Development of the proposed rules involved consultation with the Michigan Board of Medicine, whose members include small business employees.

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

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

There are no small businesses affected by the proposed rules. Those affected are individuals who are engaged in the practice of genetic counseling.

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

Licensees bear the cost and receive the 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.

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.

Applicants and licensees will continue to have a cost related burden associated with licensing, renewal, or relicensure, as well as costs related to ABGC or ABMGG certification. The cost of licensure for a Temporary – Licensed Genetic Counselor is $280.00. The cost of renewal for a Temporary – Licensed Genetic Counselor is $50.00. The cost of licensure for a Genetic Counselor is $392.00. The cost of renewal for a Genetic Counselor is $162.00. The cost of relicensure for Temporary – Licensed Genetic Counselor is $300.00. The cost of relicensure for a Genetic Counselor is $412.00.

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

The rules affect all individuals who seek licensure as genetic counselors.

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

The fees involved will be like those incurred in other regulated professions.

30. 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.

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

32. 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.

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 department does not expect any disproportionate effect on any individuals or businesses as a result of their industrial sector, segment of the public, business size, or geographical 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.

American Board of Genetic Counseling, Inc.:
https://www.abgc.net/

American Board of Medical Genetics and Genomics:
http://abmgg.org/

Council for Higher Education Accreditation (CHEA):
https://www.chea.org/

National Society of Genetic Counselors:
https://www.nsgc.org/

United States Department of Education Office of Postsecondary Education:
https://www2.ed.gov/about/offices/list/ope/index.html

Illinois:
https://www.idfpr.com/profs/GenCounselor.asp

Indiana:
https://www.in.gov/pla/professions/genetic-counselors/

Minnesota:
https://mn.gov/elicense/a-z/?id=1083-257076#/list/appId//filterType//filterValue//page/1/sort//order/

Ohio:
https://med.ohio.gov/Apply/Genetic-Counselor-GC

Pennsylvania:
https://www.dos.pa.gov/ProfessionalLicensing/BoardsCommissions/Medicine/Pages/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 estimate was necessary.

Alternative to Regulation

35. 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.

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.

Since statute mandates the rules, private market-based systems cannot serve as an alternative. The licensing and regulation of genetic counselors are state functions, so a regulatory program independent of state intervention cannot be set up. One could consider genetic counseling 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 individual accountable for harm done to patients.

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.

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

38. 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.