Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: State Medical Board of Ohio

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Regulation/Package Title (a general description of the rules' substantive content):

Genetic Counselors-Licenses and Collaboration Agreements

Rule Number(s): 4778-1-01, 4778-1-02, 4778-1-03, 4778-1-05

Date of Submission for CSI Review: 1/14/25

Public Comment Period End Date: 1/31/25

Rule Type/Number of Rules:

New/___ rules
No Change/__3_ rules (FYR? _y__)
Amended/__1__ rules (FYR? _y__)
Rescinded/____ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☐ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

   4778-1-01: Definitions

   This rule sets forth the definitions of the "Board" and "rare disease" which are used in the chapter. No changes are proposed.

   4778-1-02: Application for a License

   This rule sets forth the requirements for an application for a license to practice as a genetic counselor. The rule is proposed to be amended to correct the reference to Rule 4731-4-02 regarding criminal records checks.

   4778-1-03: Special Activity License

   This rule sets forth the requirements for a genetic counselor to obtain a special activity license in Ohio. No changes are proposed.

   4778-1-05: Collaboration Agreement

   This rule sets forth the requirements for a collaborative agreement between a physician and genetic counselor. No changes are proposed.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

4778-1-01: Authorized by: 4778.12, Amplifies 4778.09

4778-1-02: Authorized by: 4778.12, Amplifies 4778.03, 4778.08

4778-1-03: Authorized by 4778.12, Amplifies 4778.09

4778-1-05: Authorized by 4778.12, Amplifies: 4778.11

4. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
If yes, please briefly explain the source and substance of the federal requirement.

   No. The regulations do not implement a federal requirement.

5. **If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   Not applicable.

6. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

   Section 4778.12, Ohio Revised Code, requires the medical Board to adopt rules to implement and administer Chapter 4778 of the Revised Code. The proposed rules set forth the requirements for licensure application, collaborative agreements, and special activity certificates for genetic counselors.

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

   The success of the rules will be measured by compliance by regulated parties and minimal questions for interpretation of the rules.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.
   No.

Development of the Regulation

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
If applicable, please include the date and medium by which the stakeholders were initially contacted.

   The rules were approved for initial circulation by the Medical Board in March 2024. The rules were posted on the Board's website and sent via e-mail to individuals who have asked to be notified of the Board's rule updates. These include representatives of the Ohio State

Medical Association, Ohio Hospital Association, Ohio Osteopathic Association, and the Academy of Medicine of Cleveland and Northern Ohio.

10. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

    No input was received.

11. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

    When the rules were first developed in 2013, a working group assisting with the rules used scientific data to define "rare disease".

12. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?** ***Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.***

    The rules are largely proposed as no change rules. The only amendment is to correct a rule reference that was updated. There are minimal questions from the regulated licensees regarding these rules, so no alternative regulations were considered.

13. **What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

    The Medical Board is the only entity regulating the practice of genetic counselors.

14. **Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

    The Medical Board will post the updated rules on the website and send to interested parties via e-mail. Information regarding the updated rules will be provided to licensees via a monthly electronic newsletter.

Adverse Impact to Business

15. **Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**
    a. **Identify the scope of the impacted business community, and**
       Genetic counselors are the impacted business community.
    b. **Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).**
       The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a

representative business. Please include the source for your information/estimated impact.
The adverse impact to genetic counselor applicants and licensees are the initial and renewal application fees which are set by statute at $200 for initial licensure and $150 every two years for renewal.

16. **Are there any proposed changes to the rules that will <u>reduce</u> a regulatory burden imposed on the business community? Please identify. *(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).***

    The rules do not have proposed changes that will reduce the regulatory burden. The rules closely follow the statutes for genetic counselor licenure.

17. **Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**

    The rules are designed to facilitate the licensure and renewal processes for genetic counselors by providing needed information. The definitions rule defines a necessary term.

Regulatory Flexibility

18. **Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

    The rules are uniformly applicable to genetic counselors.

19. **How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

    Due process requires the rules to be uniformly applied and violation of the rules is not a paperwork violation.

20. **What resources are available to assist small businesses with compliance of the regulation?**

    The Medical Board staff is available to answer questions related to the rules.

4778-1-01 **Definitions.**

For purposes of Chapter 4778. of the Revised Code and the rules promulgated thereunder, the following definitions apply:

(A) “Board” means the state medical board of Ohio.

(B) “Rare disease” means any disease affecting approximately one in one thousand five hundred people.

4778-1-02 **Application for a license.**

(A) An applicant for an initial license or initial license designated as a supervised practice license as a genetic counselor shall submit an application under oath in the matter prescribed by the board and provide such other facts and materials as the board requires.

(B) No application shall be considered filed, and shall not be reviewed, until the non-refundable application fee provided for in division (A) of section 4778.03 of the Revised Code has been received by the board.

(C) All application materials submitted to the board by applicants may be thoroughly investigated. The board may contact individuals, agencies, or organizations for recommendations or other information about applicants as the board deems necessary. Applicants may be requested to appear before the board or a representative thereof as part of the application process.

(D) An application for an initial license shall be considered to be complete when all of the following requirements are met:

(1) The application fee provided in section 4778.03 of the Revised Code and all documentation required to demonstrate compliance with division (B) of section 4778.03 of the Revised Code has been received by the board;

(2) The applicant has complied with the requirements of paragraph (A) of rule ~~4778-2-02~~4731-4-02 of the Administrative Code and the board has received the results of the criminal records checks;

(3) The board is not conducting an investigation, under section 4778.18 of the Revised Code, of evidence appearing to show that the applicant has violated section 4778.14 of the Revised Code or applicable rules adopted by the board.

(E) An application for an initial license designated as a supervised practice license shall be considered to be complete when all of the following requirements are met:

(1) The applicant has complied with the requirements of paragraph (D) of this rule, except that the applicant is not required to demonstrate certification as a genetic counselor;

(2) The board has received documentation that the applicant is in active candidate status with the American board of genetic counseling.

(F) If an applicant fails to complete the application process within six months of initial

application filing, the board may notify the applicant in writing of its intention to consider the application abandoned. If no response to that notice is received by the board within thirty days, the board shall consider the application as abandoned and no further processing shall be undertaken with respect to that application.

4778-1-03 **Special activity license.**

(A) "Current unrestricted license," as that phrase is used in section 4778.09 of the Revised Code and this rule, means a license or other authority to practice that was issued by the appropriate entity or governmental body of another state or territory which lawfully permits the applicant to practice as a genetic counselor without governmental restrictions or limitations.

(B) The secretary of the board or, in his or her absence, another member of the board designated by the board, shall determine whether an applicant for a special activity license meets the requirements of section 4778.09 of the Revised Code. In making the determination, the secretary of the board or board designee shall take into consideration all of the following:

(1) Whether the practice in this state by the applicant will be associated with a rare disease;

(2) The existence of any information warranting investigation prior to issuance of the special activity license;

(3) Any available information regarding prior performance by the applicant while practicing in this state.

4778-1-05 **Collaboration agreement.**

(A) The collaboration agreement provided for in division (B) of section 4778.11 of the Revised Code shall meet all of the following criteria:

(1) The agreement shall be a written statement identifying and signed by the collaborating physician and genetic counselor who are party to the agreement.

(2) The agreement shall contain a general statement of the procedures, decision criteria, or categories of care that a genetic counselor is to follow when ordering genetic tests or other evaluations.

(3) The agreement shall provide for a selection of the most appropriate, accurate, and cost-effective methods of diagnosis.

(B) A collaborative agreement must be reevaluated at least every two years. If any modification to the agreement is made, the agreement must be re-executed as provided in paragraph (A)(1) of this rule.

(C) A signed copy of the collaborative agreement must be maintained by all parties and available for inspection by the board upon request.