Ohio | Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Joseph Baker, Director

Business Impact Analysis

Agency, Board, or Commission Name: The Ohio Department of Health

Rule Contact Name and Contact Information:

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

3701-70 Fetal Infant Mortality Review

Rule Number(s): 3701-70-01, 3701-70-02, 3701-70-03, 3701-70-04

Date of Submission for CSI Review: September 12, 2023

Public Comment Period End Date: October 12, 2023

Rule Type/Number of Rules:

New/__X_ rules

No Change/____ rules (FYR? ___)

Amended/____ rules (FYR? ___)

Rescinded/____ rules (FYR?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.

   - The Ohio Department of Health (ODH) established the Ohio Fetal Infant Mortality Review (FIMR) program to comprehensively assess the causes and factors that contribute to fetal and infant deaths so that recommendations can be made to prevent future deaths. It was officially established by O.R.C. 3701.70-3707.99. Rule 3701-70-01 (Definitions) provides definitions of relevant vocabulary.
   - Rule 3701-70-02 (Board members and meetings) outlines the process for assessing board membership, criteria for selected case review, and board meetings.
   - Rule 3701-70-03 (Confidentiality) establishes that all records, reports, or other information presented to the FIMR board, all statements made by board members during board meetings, and all work products and data submitted by the board are confidential and not public record.
   - Rule 3701-70-04 (Reporting) outlines the data elements required for data collection and review.

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.**

   O.R.C. 3701.049; O.R.C. 3707.70-3707.99.

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.

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)?**

   The Ohio Department of Health has been supporting local boards to conduct Fetal Infant Mortality Review since 2014. These rules establish assurances and protection for implementing the program to achieve its goals in preventing fetal and infant deaths.

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

   ODH will monitor the processes outlined in the rules to ensure compliance through submission of county reports annual reports and data recorded in the case reporting database.

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.

   Numerous stakeholders were included throughout the time that ODH worked on drafting these rules. ODH sought direction from the FIMR programs at the state and national level. The draft rules were sent to maternal and child health stakeholders interested in FIMR so they could provide input. On August 5, 2020, ODH conducted an online feedback session that included FIMR board members and other interested parties. Their direction and comments informed the draft rules and changes were made to language and level of detail provided.

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

    As noted in question 9, many stakeholders were engaged throughout the process of developing these rules. Feedback was incorporated into the draft rules.

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?

Scientific data does not apply for these rule drafts.

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.
None, the earmark language in O.R.C. 3701.049 and O.R.C. 3707.70-3707.99 requires ODH to adopt rules. The Agency did not consider performance-based regulation, specifically, because the intent of this rules package is to identify definitions and process guidelines for the implementation of FIMR.

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

ODH is the agency with authority for the FIMR program; thus, overlap is unlikely.

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.

ODH will continue to support the FIMR program and monitor compliance with the rules.

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
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.

(a) Impacted parties include but are not limited to entities from whom local FIMR teams request medical, social service, law enforcement and other case-related records.
(b) The rules establish authority for requesting records so additional staff time for those entities providing records may be required to comply.
(c) Local FIMR team estimates indicate a small commitment of time for the compilation of records requested. There is a small number of fetal infant deaths reviewed in Ohio annually, so the impact on any individual entity would be minimal.

16. **Are there any proposed changes to the rules that will reduce 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).*** This rules package establishes the rules rather than proposes changes; however, these rules will formally establish guidelines for the implementation of FIMR and identify relevant definitions, thus reducing the burden on local FIMR teams to determine process and reporting requirements.

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

    These draft rules have minimal adverse impact to entities providing case information to local FIMR teams. The public health impact of fetal and infant mortality is critical and the FIMR program is designed to collect and analyze the data to prevent future deaths.

Regulatory Flexibility

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

    No.

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?**

    These rules do not impose fines or civil penalties.

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

    Technical assistance and program consultation will be provided by ODH staff as requested/necessary.

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

3701-70 Fetal Infant Mortality Review

Rule Number(s): 3701-70-01

Date of Submission for CSI Review: 02/13/2024

Public Comment Period End Date: 03/13/2024

Rule Type/Number of Rules:

New/_X_ rules
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    As noted in question 9, many stakeholders were engaged throughout the process of developing this rule. Feedback was incorporated into the draft rules.

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    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.
None, the earmark language in O.R.C. 3701.049 and O.R.C. 3707.70-3707.99 requires ODH to adopt rules. The Agency did not consider performance-based regulation, specifically, because the intent of this rule is to identify definitions relevant to the implementation of FIMR.

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    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.
    Rule 3701-70-01 provides definitions of vocabulary relevant to Fetal Infant Mortality Review (FIMR) and has no impact on any parties. This rule identifies the definitions relevant to the data collection process outlined in Rules 3701-70-02 through 3701-70-04.

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).***
    This rule establishes the rule rather than proposes any changes; however, this rule will formally identify relevant definitions related to the implementation of FIMR.

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

    This drafted rule has minimal adverse impact to entities providing case information to local FIMR teams. The public health impact of fetal and infant mortality is critical, and the FIMR program is designed to collect and analyze the data to prevent future deaths.

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