Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*
Joseph Baker, *Director*

Business Impact Analysis

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

Rule Contact Name and Contact Information: Tyler Herrmann, tyler.herrmann@odh.ohio.gov

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

Reporting requirements for diagnosis and treatment of gender-related conditions.

Rule Number(s): 3701-3-17

Date of Submission for CSI Review: 01/24/24

Public Comment Period End Date: 2/5/24

Rule Type/Number of Rules:

New/ X rules — **No Change/ rules (FYR?)**

Amended/ rules (FYR?) — **Rescinded/ rules (FYR?)**

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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 draft regulation imposes reporting requirements for the diagnosis and treatment of gender-related conditions.

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.**

   3701.13, 3701.23

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.**

   N/A

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)?**

   Preservation of the life and health of the people of Ohio, including children.

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

   Through data and reporting.

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.

   N/A

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

    ODH staff participated in meetings with hospitals and physicians providing care for gender-related conditions and with children (and their parents) who have received such care.

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?**

    Medical expertise of ODH physicians.

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.
    N/A

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

    No duplicate regulation exists.

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.**

    Internal plan for receiving and analyzing required reports.

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.

There are no fees, penalties will only exist in cases of non-compliance, staff time will be required for submission of reports.

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).***

No.

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

Necessary for the preservation of the life and health of the people of Ohio, including children.

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?

As required by law.

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

N/A.

Common Sense Initiative

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Business Impact Analysis

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

Rule Contact Name and Contact Information: Tyler Herrmann, tyler.herrmann@odh.ohio.gov

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

Quality Standards for Gender Transition Treatment at Hospitals

Rule Number(s): 3701-59-07

Date of Submission for CSI Review: 1/24/24

Public Comment Period End Date: 2/5/24

Rule Type/Number of Rules:

New/ X **rules** — **No Change/**____ **rules (FYR?** ___**)**

Amended/____ **rules (FYR?** ___**)** — **Rescinded/**____ **rules (FYR?** ___**)**

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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 draft regulation imposes quality standards for the provision of care for gender-related conditions.

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.**

   3701.13, 3722.06

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?**
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   No.

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   N/A

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)?**

   Preservation of the life and health of the people of Ohio, including children.

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

   Through data and reporting and through complaint-based and regular inspections.

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?**
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   No.

Development of the Regulation

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
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   N/A

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

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

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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?

As required by law.

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N/A.

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Business Impact Analysis

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

Rule Contact Name and Contact Information: Tyler Herrmann, tyler.herrmann@odh.ohio.gov

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

Quality Standards for Gender Transition Treatment at Hospitals

Rule Number(s): 3701-59-06

Date of Submission for CSI Review: _____

Public Comment Period End Date: 2/5/24

Rule Type/Number of Rules:

New/ X **rules** — **No Change/**____ **rules (FYR?** ___**)**

Amended/____ **rules (FYR?** ___**)** — **Rescinded/**____ **rules (FYR?** ___**)**

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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 draft regulation disallows gender reassignment surgery and genital gender reassignment surgery for minors.

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.**

   3701.13, 3722.06

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?**
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   No.

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   No.

Development of the Regulation

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
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10. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

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    No.

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

    Necessary for the preservation of the life and health of the people of Ohio, including children.

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?**

    As required by law.

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

    N/A.

Common Sense Initiative

Mike DeWine, *Governor*
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Joseph Baker, *Director*

Business Impact Analysis

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

Rule Contact Name and Contact Information: Tyler Herrmann, tyler.herrmann@odh.ohio.gov

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

Quality Standards for Gender Transition Treatment at Health Care Facilities

Rule Number(s): 3701-83-60

Date of Submission for CSI Review: _____

Public Comment Period End Date: 2/5/24

Rule Type/Number of Rules:

New/ X **rules** — **No Change/**____ **rules (FYR? ___)**

Amended/____ **rules (FYR? ___)** — **Rescinded/**____ **rules (FYR? ___)**

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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 draft regulation disallows gender reassignment surgery and genital gender reassignment surgery for minors.

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.**

   3701.13, 3702.30

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?**
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   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.**

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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)?**

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Rule Number(s): 3701-83-61

Date of Submission for CSI Review: 1/24/24

Public Comment Period End Date: 2/5/24

Rule Type/Number of Rules:

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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.

There are no fees, penalties will only exist in cases of non-compliance, staff time will be required for submission of reports. Required care plans and staff should not add additional costs because we have been told these resources are already in place. However, providers may have increased cost if they hire or contract with additional staff to ensure compliance with the multi-disciplinary quality of care components.

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).*

No.

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

Necessary for the preservation of the life and health of the people of Ohio, including children.

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?

As required by law.

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

N/A.