



Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Mental Health and Addiction Services (OhioMHAS)

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

Gender transition care

Rule Number(s): O.A.C. 5122-16-19 and 5122-14-12.1

Date of Submission for CSI Review: 2/7/2024

Public Comment Period End Date: 2/14/2024

Rule Type/Number of Rules:

New/ 2 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Rescinded/ rules (FYR?)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.

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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.

Both rules prohibit providers from delivering certain gender transition services unless specified standards are met.

Rule 5122-26-19 applies to community behavioral health services providers and rule 5122-14-12.1 applies to private psychiatric hospitals licensed by OhioMHAS.

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.

Authorizes OhioMHAS to adopt rules – R.C. 5119.36 (community behavioral health services providers) and R.C. 5119.33 (private psychiatric hospitals)

Amplifies that authority – R.C. 5119.36 (community behavioral health services providers) and R.C. 5119.33 (private psychiatric hospitals)

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 and 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)?**

The State of Ohio has a compelling government interest to protect the health and safety of its citizens, especially children. OhioMHAS is adopting these rules as a public protection measure to ensure that community behavioral health services providers and private psychiatric hospitals are taking steps to ensure that children considering gender transition, a significant life decision, have a sufficient period of mental health counseling, involvement with a multi-disciplinary care team, and certain information before they and their parents or guardians give informed consent for gender transition services.

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

OhioMHAS periodically conducts surveys of those community behavioral health services providers and private psychiatric hospitals seeking to obtain or maintain OhioMHAS certification or licensure. During those surveys, OhioMHAS will assess compliance with the two 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?**

No.

Development of the Regulation

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

On Friday, January 5, 2024, OhioMHAS issued a bulletin to its stakeholders who subscribe to receive OhioMHAS's rule notifications asking for feedback on the two rule drafts. OhioMHAS also posted a notice on the agency's Draft Rules web site seeking public comment. During that public comment period, OhioMHAS received responses from over 5,000 parties, which included individuals and organizations as well as stakeholders.

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

Based on review and consideration of the comments during the initial public comment period, OhioMHAS has decided not to amend O.A.C. 5122-14-12 and, instead, create a supplemental rule (O.A.C. 5122-14-12.1) that addresses gender transition care by private psychiatric hospitals. The new proposed rules:

--Apply only to gender transition care for minors, defined as individuals under 18 years of age (the prior drafts distinguished some aspects of care between those individuals 21 and older and those under age 21);

--Require community behavioral health services providers and private psychiatric hospitals to employ *or have available for referral* a mental health professional and a board-certified endocrinologist. The prior draft applicable to community behavioral health services providers had required such providers to employ or have a contractual relationship with a board-certified psychiatrist and endocrinologist;

--Eliminate the requirement that the written, comprehensive, multidisciplinary care plan be reviewed by a medical ethicist.

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?

In developing these rules regarding gender transition care for minors, OhioMHAS reviewed several sources suggested by stakeholders, including the “Standards for Care for the Health of Transgender and Diverse People,” version 8 (SOC-8), published by the World Professional Association for Transgender Health (WPATH), available at <https://www.wpath.org/publications/soc>. According to SOC-8’s abstract, the recommendations in this publication were developed based on data derived from independent systematic literature reviews, background review, and expert opinions.

WPATH recommends that health care professionals assessing transgender and gender diverse individuals seeking gender-affirming treatment liaise with professionals from different professions within the field of transgender health for consultation and referral. The rules incorporate this concept by requiring community behavioral health services providers and private psychiatric hospitals to employ, or have available for referral, a board-certified endocrinologist with experience treating minors in the applicable age group. We have also added a wider range of mental health professionals to be included in the multi-disciplinary care plan instead of the initially proposed text of only allowing psychiatrists.

- 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.*

OhioMHAS did not consider alternative regulations. OhioMHAS is required by statute to adopt rules in accordance with R.C. Chapter 119 to establish certification standards for certifiable services and supports that are consistent with nationally recognized applicable standards and facilitate participation in federal programs. In addition, OhioMHAS must adopt rules in accordance with R.C. Chapter 119 prescribing minimum standards for the operation of hospitals for the care and treatment of persons with mental illnesses and establishing standards and procedures for the issuance, renewal, or revocation of full, probationary, and interim licenses.

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

OhioMHAS has been designated by the General Assembly to be the regulator of community behavioral health services providers and private psychiatric hospitals. Therefore, no other agency would have such a regulation in Ohio.

- 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.**

OhioMHAS's Office of Licensure & Certification will provide technical assistance to providers as the new rules are implemented. Rules are applied consistently during this Office's surveys conducted prior to initial certification/licensure, renewal of certification/licensure, and at other times OhioMHAS is authorized to conduct surveys.

Adverse Impact to Business

- 15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**
- Identify the scope of the impacted business community, and**
 - Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).**

The impacted business community includes community behavioral services providers (community addiction services providers and community mental health services providers defined in R.C. 5119.01) and private psychiatric hospitals. Both rules require a provider or private psychiatric hospital to employ or have available for referral a mental health professional with experience treating minors and a board-certified endocrinologist.

If a provider or private psychiatric hospital decides to employ such professionals, they will incur the costs of those individuals' salaries and benefits. However, the rules allow the providers/private psychiatric hospitals to choose to just have available *for referral* those professionals. So providers/private psychiatric hospitals do not actually have to hire any new staff if they make this choice.

There may be administrative costs related to annually demonstrating compliance with the standards specified in the rules.

16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify.

N/A.

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

OhioMHAS proposes to adopt these two rules under the authority of R.C. 5119.33 and 5119.36 as a public protection measure (see answer to question #6, above).

Regulatory Flexibility

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

No, rules regarding health and safety should be applied consistently to all community behavioral health services providers and private psychiatric hospitals regardless of size.

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?

OhioMHAS works with each provider and private psychiatric hospital to resolve issues that do not impact health and safety, as well as first-time offenses where wrongful intent is not present. Regarding the latter, OhioMHAS treats these instances as an opportunity to educate providers and hospitals about best practices.

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

OhioMHAS's Bureau of Licensure & Certification is available to work with all community behavioral health services providers and private psychiatric hospitals to ensure compliance

with the rules. The Bureau regularly provides technical assistance and educates providers and private psychiatric hospitals regarding best practices.