Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*
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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):

Private psychiatric hospitals and units

Rule Number(s): O.A.C. 5122-14-01 through 5122-14-14

Date of Submission for CSI Review: 11/28/2023

Public Comment Period End Date: 12/29/2023

Rule Type/Number of Rules:

New/___ rules

No Change/____ rules (FYR? ___)

Amended/_14, with appendix A to 5122-14-14 being new and appendix B to 5122-14-14 being rescinded___ **rules (FYR? yes__)**

Rescinded/____ rules (FYR?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.

   OhioMHAS is reviewing the rules in O.A.C. chapter 5122-14 in accordance with the five-year review requirements in R.C. 106.03. Under R.C. 5119.33(A)(1), OhioMHAS must inspect and license all hospitals that "receive persons with mental illnesses, except those hospitals managed by the department." In connection with that mandate from the General Assembly, OhioMHAS must, under R.C. 5119.33(B), adopt rules (a) prescribing minimum standards for the operation of hospitals for the care and treatment of persons with mental illnesses and (b) establishing standards and procedures for the issuance, renewal, or revocation of full, probationary, and interim licenses.

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.**
   R.C. 5119.33 and 5119.33

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.**

   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)?**

   OhioMHAS adopts these rules to comply with R.C. 5119.33(B), which requires OhioMHAS to prescribe minimum standards for the operation of hospitals for the care and treatment of persons with mental illnesses and establish standards and procedures for the issuance, renewal, or revocation of full, probationary, and interim licenses. That law was passed to ensure minimum standards for the care and treatment of persons with mental illness to be followed by private psychiatric hospitals and units in Ohio. It is consistent with the state's *parens patriae* power.

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

   The successful outcome of the inspecting and licensing requirements are private psychiatric hospitals serving Ohioans with mental illness, with a reduced number of reportable incidents or surveyed violations that impact the health and safety of those served.

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 posted to the OhioMHAS's Draft Rules web site and shared through GovDelivery with all individuals who have registered to receive rule updates from OhioMHAS (over a thousand registrants).

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

    OhioMHAS received comments from the following individuals, all of which were carefully considered from July – November 2023.

    Tracey Campbell, L.P.C.C.-S, with Firelands Health; Myron Lewis, MSW, MBA, FACHE, with Blanchard Valley Health System; Andy Sturgess-White, MBA, MPA, with the Ohio Hospital Association; Stephanie Gilligan, with the Ohio State University Wexner Medical Center; Teresa Lampl, LISW-S, with The Ohio Council of Behavioral Health & Family

Services Providers; and Kinsey Jolliff, MPPA, with MetroHealth System.

Tracey Campbell pointed out that the name of HFAP has changed to ACHC (Accreditation Commission for Health Care." OhioMHAS incorporated this change throughout the chapter.

5122-14-01 - Myron Lewis and Stephanie Gillgan asked that the definition of "transitional hold" be retained. OhioMHAS has reinserted this definition.

5122-14-04 - Myron Lewis, Andy Sturgess-White, and Stephanie Gilligan expressed concern regarding OhioMHAS's proposal to prohibit a hospital that has been issued a probationary license from admitting any patients during the term of the probationary license. There were concerns that this could increase emergency department admissions and timely access to treatment, particularly considering the state's bed capacity issues. OhioMHAS has decided to remove this proposal.

5122-14-10 – Teresa Lampl expressed concern regarding the proposal to prohibit the use of prone restraints under any circumstances and the addition of a statement that "hospital staff are not authorized to utilize prone restraint." She asked that OhioMHAS create an exemption for the use of prone restraints necessary for the safety of the patient or others and to allow prone restraint when performed to move the patient to a safer position.

Andy Sturgess-White, Stephanie Gilligan, Kinsey Jolliff, and Teresa Lamp expressed concern about the prohibition on the use of transitional holds. Specifically, they said that transitional holds are an intervention of last resort used only when there is an imminent risk of harm to either the patient, other patients, or staff when no other reasonable alternative exists. Stephanie Gilligan, in particular, said this prohibition in an acute adult inpatient psychiatric hospital endangers Harding Hospital patients, other patients, and staff. Her colleagues have found that access to the state regional psychiatric hospitals is increasingly limited and thus, patients coming to Harding have more acute needs. This, she said has led to an increase in violence against other patients and staff.

OhioMHAS recently made changes to its seclusion and restraint rules in O.A.C. 5122-26-16 and 5122-26.16.1 that were approved by JCARR. From that work, OhioMHAS has now made 5122-14-10 to be consistent with these rules. Specifically, the updates to 5122-14-10 are intended to bring OhioMHAS requirements for the use of seclusion and restraint in line with current best practices in the field. The changes to this rule also align OhioMHAS with similar rules for providers licensed by the Ohio Department of Job and Family Services, providing consistency across regulatory entities. The removal of transitional holds is being done to protect clients due to the danger of serious injury in any downward facing restraint.

Also, even before the changes to O.A.C. 5122-26-16 and 16.1, OhioMHAS prohibited the use of transitional holds in the state regional psychiatric hospitals.

5122-14-12 – Tracey Campbell and Andy Sturgess-White pointed out that there is a

behavioral health workforce shortage in Ohio and said that getting in-person psychiatric coverage two to three days a week is challenging for more rural hospitals. Tracey asked if this rule could be modified to include a more prevalent role for certified nurse practitioners. Locum tenens coverage, she said, is not a viable option in situations where psychiatrists are on leave or resign, and pointed out that such psychiatrists charge in excess of $400 per hour.

OhioMHAS has decided not the modify the rule as requested. Only a psychiatrist has the knowledge, education, and skills to oversee a hospital psychiatric unit. OhioMHAS has never even authorized a physician who is a generalist to admit patients or oversee a psychiatric unit. OhioMHAS does recognize certified nurse practitioners and physician assistants to complete histories/physicals, psychiatric evaluations, and other tasks, as long as they are practicing in accordance with law governing their professions. Psychiatric hospitals are the highest level of care in the continuum of care and the patients in them are intensely ill and need the oversight and care of a psychiatrist. No other area of medicine would expect patients with such acute needs to be seen or treated by a certified nurse practitioner or physician assistant. For example, a patient suffering from advanced heart failure would be seen by a cardiologist, not a certified nurse practitioner or physician assistant.

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?**

    The rules are based on experience with hospital accreditation standards, industry practice, and statutory requirements.

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.***

    Based on internal review and stakeholder feedback, OhioMHAS believes the current regulatory scheme is serving its intended purpose and is not in need of alternatives at this point.

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

    OhioMHAS is the regulator of private psychiatric hospitals under statute. The Ohio Department of Health licenses hospitals in Ohio, but OhioMHAS-licensed hospitals are exempt from ODH licensure under R.C. 3722.02(C)(4).

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.**

This is a renewal of existing rules. The changes OhioMHAS is proposing will be communicated to the stakeholder community prior to implementation. Beyond the rule renewal, rules are applied consistently through OhioMHAS's Bureau of Licensure and Certification during surveys to issue initial licenses, renew existing licenses, or investigate complaints.

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.

These rules impact any hospital that receives persons with mental illness, either as a standalone facility or as a unit within a general hospital.

The licensing fees are in O.A.C. 5122-14-08 and are based on size of the facility. They are not being increased. Other than that specific cost, there are employer costs for compliance. The bulk of costs are in startup facility costs related to insuring the physical plant meets rule requirements and building and fire inspections. Day-to-day there will be administrative costs related to recordkeeping, monitoring patient rights, performance improvement activities, and, when necessary, reporting incidents to OhioMHAS. Some of these costs may parallel hospital accreditation standards and requirements of payor sources (e.g., private insurance, Medicare, or Medicaid).

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).*

OhioMHAS is amending O.A.C. 5122-14-03 to specify that on and after September 30, 2024, OhioMHAS-licensed beds do not also need to be registered with the Ohio Department of Health due to the exemption from ODH registration in R.C. 3722.02(C)(4). OhioMHAS had sought this statutory change through the main appropriations act (H.B. 33) for SFYs 2024 and 2025. The regulatory burden is reduced because licensees will not have to have licenses from two different agencies. A conforming change to reflect this amendment is in O.A.C. 5122-14-12.

OhioMHAS is rescinding appendix B to O.A.C. 5122-14-14, which required paper reporting of incident reports. The regulatory burden is reduced because licensees may report incidents electronically through the Web Enabled Incident Reporting System (WEIRS).

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

As stated above, under R.C. 5119.33(A)(1), OhioMHAS must inspect and license all hospitals that "receive persons with mental illnesses, except those hospitals managed by the department." In connection with that mandate from the General Assembly, OhioMHAS must, under R.C. 5119.33(B), adopt rules 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." So OhioMHAS is implementing a statutory requirement. Further, OhioMHAS's standards are a mechanism to advocate for a vulnerable population in our state (individuals with mental illness).

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 to all providers 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 to resolve issues that do not impact patient health and safety, as well as first-time offenses where wrongful intent is not present. Regarding the latter, OhioMHAS treats these as an opportunity to teach the provider best practices.

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

OhioMHAS's Bureau of Licensure and Certification works with all hospitals to gain an understanding of what is required for safe operations and will assist them in finding the appropriate resources.