

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Mental Health and Addiction Services_____

Regulation/Package Title: Licensing of Private Psychiatric Hospitals and Units

Rule Number(s): 5122-14-01 to 14, excepting 08 and 09._____

Date: 10-6-16_____

Rule Type:

☐ New

☒ 5-Year Review

☒ Amended

☐ Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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Regulatory Intent

1. 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 Mental Health and Addiction Services (Department) is reviewing the rules in OAC Chapter 5122-14 in accordance with the five-year rule review requirements of ORC Section 106.03. The Department is required by ORC Section 5119.33 to inspect and license all hospitals that receive mentally ill persons, except those hospitals managed by the Department.

The Department has reviewed the rules regarding the licensing of psychiatric hospitals and is proposing the following:

5122-14-01 – This rule is for definitions and applicability. A general applicability statement and statement that all definitions in this rule apply to this Chapter have been inserted, and corresponding statements removed from individual rules in the Chapter. Definitions have been updated to be consistent with statutory usage, and other statutory references have been updated.

5122-14-02 – This rule has only had the applicability and definitions statements removed, along with the internal references updated. It continues to require each Department licensed hospital to be accredited by a national accreditation body.

5122-14-03 – This rule sets forth the licensing procedures, and has only had the applicability and definitions statements removed, along with the internal references updated.

5122-14-04 - This rule sets forth the classifications of licenses, and has only had the applicability and definitions statements removed, along with the internal references updated.

5122-14-05 – This rule sets forth the termination of license procedures. Added to the reasons for which a license may be refused or not renewed are provisions for the submission of false or misleading information, citations for a pattern of serious noncompliance with statutes or rules, or the revocation or denial of previous license to operate in certain circumstances. The rule also now makes it clear that submission of incomplete materials for an application is a failure to submit an application, and not a denial or revocation of the license by the Department. The rule also now states that once administrative proceedings to deny or revoke licenses have begun, the correction of deficiencies is not a bar to continuing the administrative process.

5122-14-06 – This rule sets forth the requirements to display the license and is unchanged except for the removal of the definition and applicability statements.

5122-14-07 - This rule sets forth waiver procedures and is unchanged except for the removal of the definition and applicability statements.

5122-14-10 – This rule sets forth the patient safety and physical plant requirements. In addition to the removal of the definition and applicability statements, the rule also has a new statement not allowing the use of any seclusion or restraint technique that would retraumatize an individual. The chemical restraint definition is removed in order to allow the definition in 5122-14-01 to be controlling.

5122-14-11 – This rule sets forth patient’s rights. Removed statement in (B) stating number of rights. Right of privacy is amended to include no closed circuit monitoring in bedrooms and bathrooms. Ohio legal rights service has been updated to Disability Rights Ohio.

5122-14-12 – This rule sets forth program and discharge planning requirements. The only changes are the removal of definitions and applicability statements, and updating references.

5122-14-13 – This rule sets forth medical records and documentation requirements. The rule is being amended to add that a physician's assistant, certified nurse practitioner, or clinical nurse specialist may conduct the medical history, physical examination, and psychiatric examination within their scope of practice.

5122-14-14 – This rule is being updated with correct statutory references and references to Disability Rights Ohio.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

ORC 5119.33

3. 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.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Not applicable.

5. 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 Department is carrying out its statutory duty to insure that minimum standards for the care and treatment of mentally ill persons are established and followed by hospitals in the state of Ohio.

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6. 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 licensed hospitals serving Ohio's mentally ill community, with a reduced number of reportable incidents or surveyed violations that impact that health and safety of those served.

Development of the Regulation

7. 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 Department shared the rules with and requested assistance on reviewing the rules from the Ohio Hospital Association (OHA) on July 11, 2016. OHA shared the request with their inpatient psychiatric providers and provided feedback.

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

The response from OHA and its members was generally positive. There were three items that were specifically addressed in their comments:

- “The definition of chemical restraint sounds odd. The description of the biological mechanism just seems too restrictive.”
- “The term “Disability Ohio” referring to behavioral health patients is a dated term of art that should probably not be in rule.”
- “There are a lot of renewals for the licensure office to process timely; is it possible to make the license term two or three years?”

The chemical restraint definition being adopted in these rules is being adopted to be consistent with other usages in both this Department's rules and across other agency usage. The definition is consistent with that being used by the Ohio Department of Health in OAC 3701-17-01, 3701-17-59, and 3701-64-01.

Disability Rights Ohio is the successor organization to Ohio Legal Rights Service, and is one of the organizations with standing for involvement in patient rights issues.

While the Department is cognizant of licensing issues that hospitals face, the licensing term is set by statute and is not an administrative rule term. (ORC 5119.33(B))

9. 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.

10. 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?

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

11. Did the Agency specifically consider a performance-based regulation? Please explain. *Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.*

Where possible the Department attempts to use performance-based rules, however to meet the statutory goal of protecting patient health and safety it is often necessary to define the process or be exact in terms of how service is to be delivered. When rules are process based, they are reviewed to be patient outcome focused.

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

These rules apply only to hospitals that admit mentally ill persons per statute, or those portions of hospitals which do admit such persons.

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

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

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- a. Identify the scope of the impacted business community;
- b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and
- c. Quantify the expected adverse impact from the regulation.

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 mentally ill persons, either as a standalone facility or as a unit within a general medical facility.

There is licensing fee, based on the size of the facility, in a rule not up for renewal at this time. 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 in recordkeeping, monitoring patient rights, performance improvement activities, and when necessary following incident reporting requirements. Some of these costs may parallel hospital accreditation standards requirements and requirements of payer sources (such as insurance contracts.)

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

The statutory requirement to set standards for the care and treatment of mentally ill persons requires an impact on the regulated community. The Department’s standards are a mechanism utilized to advocate for the vulnerable mental health population.

Regulatory Flexibility

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

No, health and safety regulations should be applied to all providers regardless of their size.

17. 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?

The Department does work with each provider to resolve any issues that do not impact patient health and safety, and first-time offense or offenses where wrongful intent is not present are generally treated as a teaching opportunity.

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

The Department'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.