



Common Sense Initiative

Mike DeWine, Governor
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Business Impact Analysis

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

Rule Contact Name and Contact Information:

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

1115 Waiver Rule

Rule Number(s): 5122-29-09

Date of Submission for CSI Review: September 20, 2021

Public Comment Period End Date: October 8, 2021

Rule Type/Number of Rules:

New/___ rules

No Change/___ rules (FYR? ___)

Amended/___X___ rules (FYR? _Y_)

Rescinded/___ rules (FYR?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.

This rule sets forth the requirements of the residential and withdrawal management substance use disorder services. The rule is being amended to add programmatic details regarding the American Society of Addiction Medicine (ASAM) residential levels of care. This is being done in support of the substance use disorder 1115 waiver between the Center for Medicaid and Medicare Services (CMS) and the Ohio Department of Medicaid (ODM). A copy of the approved waiver is available <https://bh.medicaid.ohio.gov/SUD-1115>.

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.**

ORC 5119.34

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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.

Yes, the SUD 1115 waiver is a contract between Ohio and CMS regarding Ohio's Medicaid program, specifically the substance use disorder (SUD) coverage.

5. If the regulation 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 rule is required for this to be a Medicaid reimbursable service.

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

The Department monitors the number of providers of this service and the demand for the service.

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 changes in these rules are reflective of discussions and recommendations provided by members of the Ohio Medicaid SUD 1115 waiver stakeholder advisory committee. This committee is made up of representatives from the following agencies, hospitals or organizations: Abraxas, Arrowhead Behavioral Health, Behavioral Healthcare Partners of Central Ohio, CommQuest, CompDrug, Crawford-Marion ADAMHS Board, House of Hope, Maryhaven, Mental Health & Addiction Advocacy Coalition, National Alliance on Mental Illness Ohio, New Directions, Ohio Alliance of Recovery Providers, Ohio Association of Community Health Centers, Ohio Association of County Behavioral Health Authorities, Ohio Association of Health Plans, Ohio Children's Alliance, Ohio Citizen Advocates for

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Addition Recovery, Ohio Council of Behavioral Health & Family Services Providers, Ohio Recovery Housing Association, Recovery Services of Northwest Ohio, Shawnee Family Health Center, Signature Health, Sojourner Recovery Services, St. Vincent Charity Medical Center – Rosary Hall, Sun Behavioral Health, The First Step Home, The LCADA Way, and The Woodrow Project. The first time the members of the Ohio Medicaid SUD 1115 waiver stakeholder advisory committee had an opportunity to review and discuss these changes was at the June 11, 2021 Ohio Medicaid SUD 1115 waiver stakeholder advisory committee meeting. Prior to that date, a number of targeted workgroups under the Ohio Medicaid SUD 1115 waiver stakeholder advisory committee held discussions and provided recommendations not on the rule itself but on the underlying practices of treating people with substance use disorders.

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

Stakeholders provided feedback on language clarifications and the role of nurses.

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?

This rule is intended to help providers certified by OhioMHAS for this service in implementing the American Society of Addiction Medicine (ASAM) criteria when providing healthcare to individuals with substance use disorders. ASAM is an evidence based practice.

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?

Not applicable.

13. 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.

Rule is performance based.

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

OhioMHAS is the regulator of Mental Health and Addiction services by statute.

15. 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.

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The Department has been active in discussing the proposed changes with stakeholders, and will continue that communication throughout the rule amendment process.

Adverse Impact to Business

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

a. Identify the scope of the impacted business community; and

This rule will apply to any provider of addiction services that wishes to provide this type of service.

b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and

Providers must meet the requirements of the rule. The adverse impact from the changes in the rule will come from the necessary adjustments to meet the increased service requirements.

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.

There are approximately 200 businesses certified by OhioMHAS for the residential and withdrawal management substance use disorder services. Estimating that there are three full time equivalent (FTEs) clinical supervisors at each business means there are approximately 600 FTEs who could potentially need some level of training on the ASAM Criteria. ASAM offers an 8 hour course for \$199.00 for non-members. Approximately \$120,000 would be needed to train all of these individuals. To accommodate training of additional staff at businesses certified by OhioMHAS for this service, we could reasonably add an additional 1,200 people to the list of those who could benefit from some training. That would result in an additional need for \$240,000. It is reasonable to project that the training needs across the entirety of the regulated population would be

less than \$500,000.

The ASAM Criteria 8-Hour Online Course

★★★★★ 4.75 (48 votes)

Overview

Getting Started

Course Introduction

Faculty

Course Content (9)

How to Claim
Credits

Credits and
Disclosures

Refunds,
Cancellations, ADA
Accommodations

Fees

Fees

Non-Member: \$199.00

ASAM Member, Retired, Early Career Physician: \$149.00

ASAM Resident, Student, Associate Members: \$99.00

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

The provision of this service must be done in a proper fashion in order to protect the health and safety of clients.

Regulatory Flexibility

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

Not applicable.

- 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?**

The Department offers technical assistance to those entities that need it when adjusting to changes in the service requirements.

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

The Department has and will continue to make itself available to providers.

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