



Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: 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):

Permanent rules related to telehealth and COVID-19

Rule Number(s): 5122-21-03, 5122-29-10, 5122-29-29, 5122-29-31, 5122-30-27, 5122-40-07, 5122-40-09, and 5122-40-12.

Date of Submission for CSI Review: 8/7/2020

Public Comment Period End Date: 8/21/2020

Rule Type/Number of Rules:

New/___ rules

No Change/___ rules (FYR? ___)

Amended/___8___ rules (FYR? N___)

Rescinded/___ rules (FYR?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

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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.

The rule package is intended to implement on a permanent basis emergency rules that were adopted, and which expanded the use of telehealth and increased behavioral health providers responsiveness to COVID-19. These changes are being adopted as permanent rules, and will be reevaluated at the end of the COVID pandemic.

The following changes are being adopted:

5122-21-03 – This rule is being amended allow PASRR level II evaluations to occur as desk reviews instead of face-to-face during a declared state of emergency, such as during COVID-19 or a natural disaster. *It should be noted that the PASRR program rule typically does not meet criteria for an adverse impact to business when adopting rules but*

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is included in this rule package for efficiency as it is being filed in the same package as other rules that do qualify for review.

5122-21-03 – Amending the PASRR rule to allow face-to-face determinations during the COVID-19 Pandemic

5122-29-10 – Removing the face-to-face requirement for this service in order to allow for telehealth delivery.

5122-29-29 – The rule is being amended to allow the Department to lower the required fidelity scores during extraordinary circumstances.

5122-29-31 – This rule is being refiled from the emergency rule to implement on a non-emergency basis the change to telehealth. Changes in definitions have been made, as well as expanding the number of services that are provided through telehealth.

5122-30-27- This rule is being amended to disallow non-voluntary discharges during the state of emergency declared due to COVID-19. Once the state of emergency is over, this provision will become inactive.

5122-40-07 – This rule is being amended to clarify that certain tests may be delayed if PPE is not available. Additionally the medical director time requirement is further defined in this rule.

5122-40-09 – This rule is being amended to add a provision for the allowance of telehealth services.

5122-40-12 – This rule is being amended to extend the disaster supply of medication and provide flexibility in storage location of medication.

- 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, 5119.36, 5119.37, 5119.40.

- 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.***

Rule 5122-21-03 implements the federal regulations for the PASRR program as delegated by the Department of Medicaid.

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

This does not exceed federal requirements.

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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)?

These rule changes are intended to ease the delivery of services during emergencies. Some changes may be rolled back after the current emergency ends through further rule changes.

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

The Department will monitor for the ability of service providers, and PASRR evaluators, to continue to provide services in a timely and safe manner during the COVID pandemic.

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 Department has communicated with stakeholders directly through email during earlier versions of these rules that were filed as emergency rules. Additionally, the rules for the OTP licensing program are being discussed with a committee of stakeholders for a different rule package.

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

The Department is working with OTP stakeholders on evaluating long-term changes to the program, however the current proposed changes are intended as interim measures for service delivery during the pandemic. OTP Stakeholders include:

Baymark
Brightview
CAAA
Central Community Health Board
CHC Addiction Services
Crossroads
Community Medical Services

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CompDrug
DeCoach
Maryhaven
New Seasons
Pinnacle
Sunrise
Ohio Council

Additionally, the Department has worked with stakeholders in identifying services to be delivered through telehealth.

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 Department is using the latest data on the need for PPE and is allowing delays in testing when PPE is not available.

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?

These changes are alternatives to normal procedures. They may be rescinded after the pandemic, but all parties will study closely how services are impacted before making long term decisions.

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.

Not applicable.

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

These rules are for areas that OhioMHAS solely regulates.

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.

These rules will continue emergency rules already in place. The Department will communicate the continuation to stakeholders.

Adverse Impact to Business

16. 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; and
- b. Identify the nature of all adverse impact (e.g., 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 changes will apply to all certified service providers, residential facilities, and licensed Opioid Treatment Providers. There should be minimal impact to the providers, as the rules are an effective expansion of their current abilities. The one exception is the inability to conduct involuntary discharges in residential facilities is suspended during declared states of emergency. This will require facilities to work with residents who are at issue during those times. Overall, even this impact should be minimal as resident fees should still be paid and will be owed at the end of the emergency.

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

The changes in the rules should be a positive impact on stakeholders and how they provide services during the pandemic and in some cases other emergencies.

Regulatory Flexibility

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

Service delivery should be the same for all providers, regardless their 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?

The Department will work providers to understand the rules and implement them better, rather than pursue administrative action for first time offenders.

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

The Department’s Office of Licensure and Certification has employees assigned to each provider who can assist with any questions that may come up with these rule changes.

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