



Common Sense Initiative

Mike DeWine, Governor
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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Medicaid (ODM)

Rule Contact Name and Contact Information:

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Regulation/Package Title: Services Provided by a Pharmacist

Rule Number(s): 5160-27-01

SUBJECT TO BUSINESS IMPACT ANALYSIS:

New:

Amended: 5160-27-01

NOT SUBJECT TO BUSINESS IMPACT ANALYSIS, INCLUDED FOR INFORMATION ONLY:

5160-8-52, 5160-27-02, 5160-27-03

Date of Submission for CSI Review: 9/16/2020

Public Comment Period End Date: 9/23/2020

Rule Type/Number of Rules:

New/ rules 0 rule

No Change/___ rules (FYR? ___)

Amended/___1___ rules (FYR? _No_)

Rescinded/___ rules (FYR?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.

5160-27-01: This rule lists and describes those providers that can render mental health and substance use disorder treatment services covered by Medicaid. The rule revision adds pharmacists, as defined in in rule 5160-8-52, as an eligible Medicaid provider type. The pharmacist must be an employee or an independent contractor of an entity described in paragraph (A)(1) or (A)(2) of the rule. Two requirements are removed as they are stated in other Medicaid program rules. The requirements regard the need for provider agencies to have a Medicaid provider agreement, the other requires a provider to update, to ODM, geographical locations of operation as they change. Other revisions, that don't involve policy changes, include replacement of existing language with new language to add clarity.

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.**

5160-27-01: [5162.02](#), [5164.02](#); [5162.03](#), [5164.02](#), [5162.371](#), [5119.391](#)

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.

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The existing rule as well as proposed changes are not necessitated by federal law; the rule is being made to update Medicaid policy and improve administration of the Medicaid benefit.

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

This rule, as well as the proposed changes in the rule, does not include provisions that are addressed in federal requirements, therefore they do not exceed any federal requirements. ODM, to support the effective and efficient administration of the Medicaid program and for the safety of Medicaid recipients, places desired policy provisions and requirements in OAC rule so they may be enforceable.

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)?

This rule states those eligible providers that can render behavioral health services to Medicaid recipients and be reimbursed for those services. The proposed revisions to the existing rule adds pharmacists as a new eligible provider type. This rule states requirements that support the effective, efficient operation of the Medicaid program by stating requirements providers must follow to support the safe provision of behavioral health services to Medicaid recipients. The proposed revisions to the rule already in effect, adds pharmacists as a new eligible provider type.

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

The success of the amendments to this rule will be measured by the extent to which pharmacists can submit claims and receive correct Medicaid reimbursement.

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 proposed rule was placed on the ODM website for review and comment for a period of time in early July 2020. Only one stakeholder provided comments on the 5160-27-01 rule, the Ohio Pharmacists Association (OPA). OPA, as well as other stakeholders, commented on the other rules in this package that are included for information only. That being the case, only comments regarding 5160-27-01 are addressed as it is the subject of the BIA.

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

OPA said that the feedback it had received from pharmacists that practice in a behavioral health setting was, in general, positive. OPA supports the philosophical approaches taken in ODM's behavioral health rules that include 5160-27-01.

As OPA's comments were supportive, ODM did not make any revisions to the proposed rule.

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?

Ohio Medicaid claims data were the main source of information used to guide the policy and budget models that undergrid these rules. This data was used to determine the fiscal impact on ODM.

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 were not applicable. ODM makes use of OAC rules to state policies and regulations so it may enforce and, when necessary, conduct program integrity activities regarding the provision of services to Medicaid recipients.

In order for Ohio Medicaid to recognize and reimburse pharmacists for services rendered to Medicaid recipients, it was necessary to include them in this eligible provider rule so the provision could be enforced.

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.*

ODM did not consider a performance-based regulation, because the nature of the regulations described in these rules do not lend themselves to a performance-based standard.

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

ODM, as the agency charged with administering the Ohio Medicaid program, is the only entity authorized to enact the regulations in these rules. ODM staff review the rules to check for the duplication of regulations

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.

The policy changes set forth in this rule will be incorporated into (1) internal Medicaid processes; (2) the Medicaid Information Technology System (MITS), which is the department's electronic claim-payment system and (3) the Provider Network Module (PNM) which will be the department's provider enrollment module. Incorporation into ODM processes and systems will ensure that the rule is applied consistently and predictably.

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;

The impacted business community includes behavioral health providers certified by the Ohio Department of Mental Health and Addiction Services and hold a provider agreement with ODM to render services to Medicaid recipients.

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

Pharmacists, as a newly eligible behavioral health provider, would need to comply with the general provisions in Chapter 5160-1 which apply to all Medicaid providers as well as those rules that address the types of services pharmacists would render. The provisions have been amended so that they are incorporated by reference to point to the rules from which the applicable regulations originate and are no longer duplicative regulations. Therefore there are no adverse impacts in the rule.

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.

As there is no adverse impact, there is no associated cost to quantify. The adverse impact in the rule was removed as the requirement was duplicative.

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

As previously stated, there is no adverse impact. This rule states requirements that support the effective and efficient operation of the Medicaid program and support the safe and appropriate provision of the described services to Medicaid recipients.

Regulatory Flexibility

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

No, to ensue uniform and consistent treatment of Medicaid providers, ODM is not able to make exemptions or provide alternative means for compliance for small businesses.

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?

These rules impose no first time paperwork sanctions on providers.

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

All Medicaid providers in need of technical assistance can contact the Medicaid Provider Assistance telephone line at 1-800-686-1516. Behavioral health providers impacted by the revisions in the proposed rules have a unique email address available to them, BH-Enroll@medicaid.ohio.gov . Providers also have access to detailed information by visiting the dedicated internet site: bh.medicaid.ohio.gov.