



## Common Sense Initiative

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

**Carrie Kuruc**, Director

### Business Impact Analysis

Agency, Board, or Commission Name: Ohio Bureau of Workers Compensation

Rule Contact Name and Contact Information:

Aniko Nagy (614) 466-3293

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

Payment for Outpatient Medication

Rule Number(s): 4123-6-21

Date of Submission for CSI Review: 03/10/2021

Public Comment Period End Date: 03/31/2021

Rule Type/Number of Rules:

New/\_\_\_ rules

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Rescinded/\_\_\_ rules (FYR?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.*

BWC adopted Rule 4123-6-21 in 1997 to establish rules for payment of outpatient medication used for the treatment of an occupational disease or injury in an allowed claim. The rule is maintained by BWC with input from the BWC Pharmacy and Therapeutics Committee.

The proposed revisions to the rule limit reimbursement for non-sterile compounded prescriptions to situations where a commercially available formulary drug becomes temporarily unavailable. Other requests for reimbursement of non-sterile compounds will be denied. The maximum reimbursement for a non-sterile compound was lowered from \$400 to \$100.

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. 4121.441(A), 4123.66(A)

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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?**

No.

*If yes, please briefly explain the source and substance of the federal requirement.*

N/A

- 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 purpose of Rule 4123-6-21 is to outline payment rules related to outpatient medication used for the treatment of an occupational injury or disease in a claim allowed by BWC or the industrial commission or recognized by a self-insuring employer. The rule equips BWC providers with information regarding prescription coverage, prior authorization requirements, and methods used to calculate prescription reimbursement.

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

Routine monitoring of prescription data from our pharmacy benefit manager.

- 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?**

No.

*If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.*

N/A

### **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 rules were published for stakeholder comment on February 5, 2021, with a comment period open through February 15, 2021, and notice was e-mailed to the following lists of stakeholders:

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- BWC's Managed Care Organizations
- BWC's Medical Services Division's medical provider stakeholder list
- BWC's Healthcare Quality Assurance Advisory Committee
- Ohio Association for Justice
- Employer Organizations
  - o Council of Smaller Enterprises (COSE)
  - o Ohio Manufacturers Association (OMA)
  - o National Federation of Independent Business (NFIB)
  - o Ohio Chamber of Commerce
- BWC's Self-Insured Division's employer distribution list
- BWC's Employer Services Division's Third-Party Administrator (TPA) distribution list
- Ohio Medical and Pharmacy Boards.

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

No stakeholder feedback was received on the proposed changes.

**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 proposed revisions to rule 4123-6-21 were based on recommendations accepted by the BWC Pharmacy & Therapeutics Committee. The committee reviews data from clinical trials, published studies, and relevant guidelines regarding medications prior to making recommendations.

**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?**

This rule applies specifically to prescription coverage for Ohio injured workers. BWC is the only state agency charged with this statutory responsibility.

**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.***

This process is not applicable to prescription reimbursement.

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

This rule only affects injured workers receiving prescription benefits from BWC. No other state agency has adopted regulations regarding what drugs are reimbursed by BWC.

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**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.**

Once the rule is approved and through the JCARR process, BWC staff impacted by the rule will be informed of the effective date. Providers caring for injured workers will be notified of the key points contained in the rule by email, fax or direct mail. They will also be provided with a link to find a complete copy of the rule.

BWC’s Medical Services Division will ensure that relevant sections of the MCO Policy Reference Guide and the Provider Billing and Reimbursement Manual are updated to reflect appropriate rule modifications.

**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;**

The prescriber and pharmacy business communities are involved with the prescribing and dispensing of medications. The impacted segments of those communities are the BWC enrolled or certified providers who prescribe and dispense medication to injured workers.

**and**

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

These revisions limit reimbursement for non-sterile compounded prescriptions to situations where a commercially available formulary drug becomes temporarily unavailable. Other requests for reimbursement of non-sterile compounds will be denied. The maximum reimbursement for a non-sterile compound was lowered from \$400 to \$100. This may reduce revenue for BWC enrolled pharmacies that request BWC reimbursement for non-sterile compounds.

**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.*

According to the annual prescription report provided by BWC’s pharmacy benefits manager, during calendar year 2020 BWC total reimbursement for non-sterile compounded prescriptions was approximately \$52,732. The proposed restrictions will prohibit

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reimbursement of these prescriptions in the future, unless reimbursement is requested due to a commercial formulary product becoming unavailable in which case BWC will reimburse up to \$100 for the compounding of the drug with equivalent active pharmaceutical ingredients until the commercial formulary product becomes available.

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

Rule 4123-6-21.2 charges the BWC Pharmacy and Therapeutics Committee to conduct regular reviews of prescription reimbursement rules and to make recommendations to the Administrator directed at improving overall efficiency and effectiveness of drug utilization. These changes to drug coverage result from that activity. Revisions are routinely made based on opportunities to improve the clinical impact, address abusive pricing practices by manufacturers or incorporate changes in federal drug regulations.

Non-sterile compounds are not FDA-approved, and have not undergone an FDA assessment of safety, effectiveness, and quality. Due to lack of supporting evidence and safety data for these products, the BWC Pharmacy and Therapeutics Committee was supportive of limiting reimbursement for these products to situations where the commercially available equivalent formulary drug becomes temporarily unavailable. Review of BWC average historical payment data for topical prescriptions supported reducing reimbursement from \$400 to \$100.

**Regulatory Flexibility**

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

No. All BWC providers are required to follow reimbursement rules outlined in 4123-6-21 if BWC is to reimburse for those prescriptions.

**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?**

N/A

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

Prescribers may utilize the BWC website for a complete list of formulary medications and any restrictions to those drugs. The BWC Pharmacy Department also maintains an email address (pharmacy.benefits@ bwc.state.oh.us ) that prescribers can use to ask questions about drug coverage.

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**Stakeholder Feedback Health Partnership Program  
OAC 4123-6-21 – Payment for Outpatient Medication**

| Line | Rule #/<br>Subject<br>Matter | Stakeholder | Draft Rule<br>Suggestions | Stakeholder Rationale | BWC Response | Resolution |
|------|------------------------------|-------------|---------------------------|-----------------------|--------------|------------|
| 1    | 4123-6-21                    |             |                           |                       |              |            |